Fiscal Impacts of Proposed 15A NCAC 02L Groundwater Rules

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<u>Fiscal Impacts of Proposed Rules</u>

Rule Citation: 15A NCAC 02L .0202 – Groundwater Quality Standards
15A NCAC 02L .0113 – Variance

DENR Division/ Commission: Division of Water Quality (DWQ)/ Environmental Management Commission (EMC)

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Impact Summary:

State government:	Yes
Local government:	Yes
Private industry:	Yes
Substantial impact:	Yes
Federal government:	No
Small business:	No

Authority: G.S. 143-214.1; 143B-282(a)(2)
G.S. 143-215.3(a)(1); 143-215.3(a)(3); 143-215.3(a)(4); 143-215.3(e); 143-215.4

Necessity: The proposed rule amendments incorporate the most recent U.S. EPA health effects data into the 1,1-Dichloroethylene (1,1-DCE) groundwater quality standard and clarify existing groundwater rule requirements that will make the rules more cost effective without sacrificing public health and safety. The North Carolina Environmental Management Commission (EMC) approved these proposed amendments on July 14, 2011.

I. Summary

There are three rule change options proposed:

1) A change in 02L .0202 (g)(59) to amend the 1,1-DCE standard from 7 ug/L to 350 ug/L;
2) A change in 02L .0202 (d) and (f) to allow the EMC to establish a standard less stringent that the maximum contaminant level (MCL) when:
    a. the MCL is not based on the most recent U.S. EPA health effects data as published in U.S. EPA's Integrated Risk Information System (http://www.U.S. EPA.gov/IRIS/);
    b. such a standard would not endanger public health and safety; and,
    c. compliance with a standard based on the MCL would produce serious hardship without equal benefit.

3) A change in .0113 to:
   a. update the Division of Water Quality mailing address, in .0113 (b)
   b. to allow the EMC to issue a state-wide variance to the 02L rules in .0113 (d); and
   c. to clarify the existing variance requirements in .0113(i).

Following public notification in the North Carolina Register, public hearings and a 60-day public comment period, the EMC will decide which of the above options, or combination of options, to adopt.

<u>Option 1:</u>
Rhodia, Inc., a global specialty chemical manufacturer that formerly operated as Rhone-Poulenc in Gastonia, North Carolina, submitted a rulemaking petition to amend the 1,1-DCE groundwater standard in 02L .0202(g)(59) from 7 ug/L to 350 ug/L based on the availability of more recent U.S. EPA health effects data. A change in this standard may result in lower compliance costs for facilities that have a release of 1,1-DCE to groundwater. However, potential compliance costs may increase for public water supply systems that use 1,1-DCE-contaminated groundwater as a source of drinking water. Parties responsible for 1,1-DCE groundwater contamination may not realize any cost savings for this change because 1,1-DCE seldom is the only pollutant that motivates cleanup activities and is often found with other chlorinated solvents. In addition, if contaminated water is currently, or could in the future be, impacting a public water supply groundwater source regulated by the NC Drinking Water Act, the company would still have to treat the water to the 7 ug/L standard. Also, there is an unresolved question regarding whether Option 1 is a legally viable solution as some believe that the EMC might not have the authority to change the standard itself.

<u>Option 2:</u>
The DWQ and EMC seek to amend 02L .0202(d) and (f) on the advice of the EMC's legal counsel that rule language is needed to allow deviation from 2L .0202(d), which requires that the groundwater standard be established at the lowest of the six criteria, one of which is the MCL. DWQ staff believe that this option would have the same impact as Option 1 because it will allow the 1,1-DCE standard to be set above the MCL but without legal challenge.

<u>Option 3:</u>
Proposed changes to 02L .0113 include the addition of a statewide variance option that would allow the EMC to consider a request for a less restrictive groundwater standard when the existing standard is based on outdated health effects data, such as the case with the existing 1,1-DCE standard. DWQ staff anticipate that the EMC will adopt Options 1 and 2, and not Option 3; however, if the EMC adopts Option 3 and not Options 1 and 2, then Rhodia, Inc. will most likely request a statewide variance to the 1,1-DCE groundwater standard because this contaminant is solely responsible for cleanup requirements and costs at the Rhodia site. At this time no other parties have been identified where 1,1-DCE is the sole contaminant driving cleanup requirements and costs at their site.

DWQ staff assumes that the benefits of adopting Option 3 would essentially be the same as adopting Options 1 and 2. The inclusion of a statewide variance may reduce the number of future variances submitted to DENR because a statewide variance would apply to sites across the state. Staff time spent reviewing and processing a single statewide variance would likely be less than staff time spent reviewing multiple variances for the same request. The party requesting a statewide variance will incur the cost of gathering the necessary data requirements.

Other proposed changes to the variance procedures in 02L .0113 include an update to the DWQ mailing address and clarification of the existing variance requirements that are not expected to result in any additional costs or benefits.

The approximate effective date of the proposed rules is January 1, 2013.

Based on outreach response from potentially impacted parties and information provided by state regulatory agencies, Rhodia is the only company immediately affected by the proposed rule changes. If Rhodia is the only company immediately affected by this rule change, and no additional costs are placed on drinking water suppliers, the costs of this proposed rule change will be approximately $5,200. Benefits, in the form of opportunity cost-savings for NCDENR and less monitoring for NCDOT will be approximately $27,000. Rhodia may experience a cost savings of up to $866,000 in the next 30 years. The 30-year net present value of the proposed rule change would be approximately $896,000. Net present value is presented over a period of 30 years since this is the estimated time it would take Rhodia to complete cleanup at the site under existing rules using pump-and-treat remediation. The risk analysis section examines additional costs and benefits that may be incurred by additional companies and water supply systems or the need for more water remediation as a result of the rule change. The full table is presented in Appendix K.

Table 1: Partial Representation of Total Costs and Benefits Associated with Proposed Rule Changes to 15A NCAC 02L .0202 Groundwater Quality Standards with Two Percent Inflation and Seven Percent Discount Rate

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**
Year Number	**0**	**1**	**2**	**3**	**4**
Costs					
Private Company Well Closure Costs	$0	$5,304	$0	$0	$0
Total Costs	***$0***	***$5,304***	***$0***	***$0***	***$0***
Benefits					
State Benefits					
DOT Reduced Monitoring	$0	$3,672	$3,537	$3,396	$3,247
DWM Opportunity Cost Savings					
Private Company Benefits					

Monitoring Cost Savings to Private Companies	$0	$5,426	$5,535	$5,646	$5,759
Operations and Maintenance Cost Savings		$0	$0	$0	$0
Total Benefits	***$0***	***$9,098***	***$9,072***	***$9,041***	***$9,006***
Net Impact (benefits-costs)	**$0**	**$3,794**	**$9,072**	**$9,041**	**$9,006**
Total Impact (benefits+costs)	***$0***	***$14,402***	***$9,072***	***$9,041***	***$9,006***
30-year Net Present Value	**$895,775**				

II. Introduction and Purpose of Rule Changes

Groundwater Classifications and Standards in 15A NCAC 02L .0200 are intended to "maintain and preserve the quality of the groundwaters, prevent and abate pollution and contamination of the waters of the state, protect public health, and permit management of the groundwaters for their best usage by the citizens of NC." It is the policy of the North Carolina EMC that the best usage of groundwaters of the state is as a source of drinking water. More than 50 percent of North Carolinians rely on groundwater as a source of drinking water.

By regulation, groundwater standards are established as the lowest concentration of the following six criteria contained in 15A NCAC 02L .0202(d) (1) – (6):
(1) Systemic threshold concentration calculated as follows: [Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)];
(2) Concentration which corresponds to an incremental lifetime cancer risk of $1x10^{-6}$;
(3) Taste threshold limit value;
(4) Odor threshold limit value;
(5) Maximum contaminant level; or
(6) National secondary drinking water standard.

The maximum contaminant level (MCL) of 7 ug/L for 1,1-DCE is the lowest concentration of the six criteria in 02L .0202(d) and was used to establish the groundwater standard. MCLs are federal drinking water standards established by the U.S. EPA Office of Water and are applicable to public water supply systems regulated under the Federal Safe Drinking Water Act.

In March 2011, McGuireWoods, on behalf of Rhodia Inc., submitted a rulemaking petition to the Division of Water Quality Director requesting amendment of the groundwater quality standard for 1,1-DCE contained in 15A NCAC 02L .0202(g)(59) from 7 ug/L to 350 ug/L. The Petition was submitted in accordance with N.C.G.S. 150B-20 and 15A NCAC 02I .501, which allows any person to petition the Director to adopt, amend or repeal an existing rule of the EMC. A copy of the Petition is included Appendix A. A summary of the Petition and background information is included in Appendix B.

1,1-Dichloroethene (DCE) is an industrial chemical not found naturally in the environment. Companies use 1,1-DCE to make plastics, such as flexible films like food wrap, flame retardant coatings, adhesives, and packaging materials. Long term or chronic exposure to 1,1-DCE by drinking 1,1-DCE-contaminated groundwater may cause liver toxicity. 1,1-DCE shows equivocal evidence of carcinogenicity by the oral route of exposure; therefore, it is not known if exposure to 1,1-DCE increases the risk of cancer in humans (http://www.U.S. EPA.gov/iris/subst/0039.htm http://water.U.S. EPA.gov/drink/contaminants/basicinformation/1-1-dichloroethylene.cfm#one).

The major source of 1,1-DCE in drinking water is discharge from industrial chemical factories.

The U.S. EPA, the federal agency that establishes MCLs, acknowledges that updated health effects data support increasing the 1,1-DCE MCL to 350 ug/L. However, U.S. EPA decided not to update the MCL for 1,1-DCE citing that any potential revision is not likely to provide a meaningful opportunity for cost-savings or health risk reduction to public water systems and their customers http://edocket.access.gpo.gov/2010/pdf/2010-6624.pdf.

Rhodia's Petition was presented at the May 2011 EMC Groundwater Committee meeting and the July 2011 EMC meeting. Information is available on the EMC Web site at http://portal.ncdenr.org/web/emc/agenda/2011/home. On July 14, 2011, the EMC approved Rhodia's petition and initiated rulemaking to amend the 1,1-DCE groundwater standard as requested. At the July meeting, the EMC granted approval to the DWQ to initiate rulemaking to adopt proposed rule language in one or more of the three options discussed in this fiscal note:

Option 1: 02L .0202 (g) (59),
Option 2: 02L .0202 (d) and (f),
Option 3: 02L .0113 (b) through (i)

Option 1:
The purpose of changing the 1,1-DCE groundwater standard from 7 ug/L to 350 ug/L is to incorporate the most up-to-date health effects data. The proposed change to 02L .0202(g)(59), would have the same impact as the one anticipated for the proposed changes in .0202(d) and (f), assuming that the latter change would only lead to the relaxation of the 1,1-DCE standard to 350ug/L. To this end, only the impact from .0202(d) and (f) is discussed in this fiscal note.

Option 2:
The purpose of the proposed changes to 02L .0202(d) and (f) is three-fold: 1) to ensure that the most recent U.S. EPA health effects data are used in establishing groundwater quality standards; 2) to ensure that the standard is protective of public health and safety; and, 3) to ensure that the standard is not overly burdensome to regulated parties. If the lowest concentration of the six regulatory criteria for establishing a standard in .0202(d) is the Maximum Contaminant Level (MCL) and the MCL is not based on the most recent U.S. EPA health effects data in .0202(e), then the proposed rule will allow the MCL to be eliminated for consideration as the groundwater standard. At this time, 1,1-DCE is the only standard that is being changed, but this proposed rule change may lead to additional groundwater quality standard changes in the future.

Option 3:
The purpose of the proposed amendments to 02L .0113 is to update the DWQ mailing address, clarify the existing variance requirements and to allow the EMC to issue a statewide variance to the 02L rules when requested. The allowance of a statewide variance presents an alternate option to Options 1 and 2 that would not change the fundamental way standards are currently established in 2L .0202(d).

The three proposed amendments are located in Appendices C, D and E, respectively. The proposed changes to the rules have been highlighted in yellow. In addition, Appendix F includes a summary of the proposed amendments and the potential economic impact.

Support letters for Rhodia's Rulemaking Petition were received from Radiator Specialty Company, Indian Trail, NC and Duncklee & Dunham Environmental Consulting & Engineering, Cary, NC. Copies are located in Appendix G and H, respectfully.

III. Costs and Benefits by Rule

Each proposed rule revision is listed below with a description of the rule, the proposed changes, and the estimated economic impact expected for various public and private entities. The existing rules serve as the baseline from which economic impacts are evaluated.

The DWQ has collected information from a number of potentially affected parties including members of the regulated community, such as power utility companies, chemical manufacturers, dry-cleaning associations, local governments, state government, treated wood industries, the poultry and pork federations, furniture manufacturers and state regulatory agencies. A list of contacted parties is located in Appendix I. Parties identified during the outreach activities that are potentially affected by the proposed rules are discussed below.

a. _15A NCAC 02L .0202 - Groundwater Quality Standards (Option 1 and 2)_
15A NCAC 02L .0202 sets out the criteria used to establish groundwater standards and provides a list of established groundwater standards. There are two proposed options to revise this language: an increase in the 1,1-DCE standard in .0202(g)(59) from 7 ug/L to 350 ug/L and a revision to .0202(d) and (f) to allow a groundwater standard to be established above an MCL, if that MCL was established using outdated U.S. EPA IRIS health effects data. Either of the option would lead to the same impact, at least in the foreseeable future.

Costs and Benefits Associated With Propose Changes to Rule 15A NCAC 02L .0202

These costs and benefits were estimated using the assumption that the change in the 2L groundwater standard would not alter the number of drinking water sources contaminated with 1,1-DCE. The Division of Water Quality believes that this is the most probable scenario. In the risk analysis section, we consider what would happen if more drinking water sources are contaminated as a result of the rule change.

i. Federal Government Impact

No increased or decreased expenditures were identified as a result of the proposed rule changes.

ii. State Impact

DWQ contacted state government agencies potentially affected by this proposal including the Department of Transportation, Department of Agriculture, Division of Waste Management, Division of Air Quality, Division of Water Quality, and Division of Environmental Health.

NCDENR reported that it would realize decreased cost due to reduced regulatory oversight.

NCDOT reported that it would realize decreased expenditures due to reduced reporting (text discussions and mapping) requirements and the other agencies reported no anticipated direct impact.

The North Carolina Department of Transportation (NCDOT)

The NCDOT has identified and attempted to quantify the economic impacts associated with the proposed 15A NCAC 02L rule changes. The program within the NCDOT that will be principally affected by this change is the Asphalt Testing Program. The NCDOT Asphalt Testing Program performs on-site testing of asphalt for department construction activities using ASTM Method D2172-88. This method requires the use of a solvent, such as trichloroethylene, 1,1,1-tetrachloroethane, or carbon tetrachloride. Solvents stored, spilled, or disposed of on-site near operating labs resulted in releases of chlorinated solvents to the environment. 1,1-DCE is a breakdown product of chlorinated solvents and has been detected in the groundwater at Asphalt Testing Sites.

Twenty-three Asphalt Testing Program sites may potentially be impacted by a change in the groundwater standard for 1,1-DCE. Groundwater at five of the 23 sites exceeds the proposed 1,1-DCE standard of 350 ug/L. NCDOT does not anticipate a significant reduction in compliance costs because other chlorinated solvents are present in the groundwater and these would have to be cleaned up regardless of the change in the standard for 1,1-DCE. However, the reporting (text discussions and mapping of 1,1-DCE) may be reduced by a limited extent at 18 sites where the 1,1-DCE concentration is below 350 ug/L. NCDOT estimates an annual savings of approximately $200 per site. DOT further estimates that one facility will cease testing each year. Savings in the first year would be $3,600 and decrease by $200 in each following year.

The NCDOT determined that no additional work efforts or cost savings would be realized as a result of the proposed revisions to .0202(d) & (f) and 02L .0113.

Division of Water Quality (DWQ)
The DWQ Aquifer Protection Section (APS) is authorized under 15A NCAC 02L and 15A NCAC 2T to issue permits that allow the discharge of waste onto land or into the subsurface under conditions outlined in the permit (non-discharge permits). If permitted facilities experience a change as a result of the rule amendment, this could potentially affect the Division's workload. Staff examined the Basinwide Information Management System (BIMS) database to estimate the number of potentially affected sites and to determine if there are any current cleanup activities on permitted sites related to the contaminant 1,1-DCE. There are no reported cleanup activities underway as a result of permitted activities. No Notices of Violation were reported for exceedances of the current standard outside the compliance boundary. Compliance boundaries at a typical DWQ permitted waste site are illustrated in Appendix J. In addition, there are 171 DWQ permitted facilities monitoring groundwater for volatile organic compounds that could include 1,1-DCE, however, there were no reports of 1,1-DCE exceeding the current standard. This information suggests that the change in standards would have no direct impacts on the division.

Division of Waste Management (DWM)
The Division of Waste Management has four sections that manage and regulate specific types of waste: The Hazardous Waste, Superfund, Solid Waste and Underground Storage Tank Sections. While 1,1-DCE is one of several constituents found in groundwater at sites regulated by DWM cleanup programs, according to DWM staff and two independent consultants, it is seldom the only driver for the assessment and/or cleanup of contaminated groundwater. Only Rhodia, Inc., was identified by the DWM as being primarily impacted by the proposed 1,1-DCE standard change.

The Superfund Section's Inactive Hazardous Waste Sites Branch is the agency with regulatory oversight of Rhodia, Inc. Increasing the 1,1-DCE groundwater standard will most likely reduce the time it takes Rhodia to come into compliance with the groundwater standard, and reduce staff time and resources needed for oversight of the facility's cleanup responsibilities.

For purposes of this analysis, it is estimated that there will be a fifteen-year reduction in the time it will take for Rhodia to cleanup 1,1-DCE groundwater contamination to the proposed 350 ug/L standard.

The annual cost-savings of staff time is $774, assuming 22 hours of staff time associated with report review and correspondence and an annual site visit for a mid-range engineer position with a total hourly compensation of $35.18.

The estimated mileage cost-saving of a yearly site visit is $60, assuming a maximum distance of 120 mile from the Mooresville Regional Office to the Rhodia site and a mileage rate of $0.50 per mile for a state-owned Ford Explorer, 4X4 at the state Motor Fleet mileage rate.
http://www.ncmotorfleet.com/documents/NewRateSheetMay2010.pdf

The total cost-savings is estimated to be $834 per year.

For Superfund sites, the 02L standard is the Applicable or Relevant and Appropriate Requirement (ARAR) for groundwater cleanup. If the proposed rule language is adopted the ARAR standard would become 350 ug/L. However, if the cleanup affects a regulated drinking water source, the drinking water standard (7 ug/L) would still be the ARAR. The party responsible for the pollution would have to clean up the groundwater to the drinking water standard. This means that no additional water treatment costs would be placed on water supply companies or local governments.

It is possible that water supply companies and local government would incur costs if they choose to use a contaminated water source after a remedial action plan is already approved. This seems highly unlikely though because these groups seek the cleanest possible source waters in an effort to contain water treatment costs.

iii. Local Government Impact

DWQ staff contacted local governments through various associations such as the NC League of Municipalities, NC Councils of Government, NC Association of County Commissioners, and state programs that regulate local government activities such as environmental cleanup and operation of publically owned wastewater treatment plants, public water supply systems and solid waste landfills. DWQ received eleven comments on the potential economic impacts of the proposed rules either directly from or on behalf of local governments. No direct costs or benefits were identified as a result of the propose rule revisions.

The proposed change to groundwater standards does not affect drinking water standards. The drinking water standard for 1,1-DCE would remain at 7 ug/L. This difference in groundwater and drinking water standards potentially may lead to future costs for publically owned and operated public water supply systems if groundwater used as a source water is contaminated above the MCL of 7 ug/L and treatment is required. DWQ staff anticipates this to be an unlikely outcome. The Division of Water Resources has identified current and future needs and resources for drinking water, including groundwater, throughout the state so most current/future drinking water sources are known (see link to plans – http://www.ncwater.org/Water_Supply_Planning/NC_Water_Supply_Plan/). Further, there have been very few MCL violations reported for 1,1-DCE. Both state and federal drinking water program data support that 1,1-DCE is not a likely problem even if the groundwater standard is raised to 350 ug/L and the MCL remains at 7 ug/L. The Risk Analysis section contains a discussion of this potential cost.

iv. Private Industry Impact

Companies that pollute groundwater in excess of the 02L .0202 Groundwater Quality Standards may be required to take corrective action in accordance with 15A NCAC 02L .0106. A 50 fold change in the 15A NCAC 02L .0202(g)(59) groundwater standard for 1,1-DCE from 7 ug/L to 350 ug/L could reduce compliance cost at sites with known groundwater contamination above the current standard of 7 ug/L and at sites where future 1,1-DCE groundwater contamination might occur or be discovered. Private companies performing groundwater remediation may experience a reduction of compliance costs in the following ways:

- As a result of a higher standard, the groundwater plume will be smaller and the length of time to cleanup will be shorter.
- A smaller plume and higher cleanup level may allow the use a more economical cleanup technology.
- A lower number of groundwater wells may be needed to determine the boundaries of the contamination.
- Monitoring wells that meet the proposed standard may be closed and no longer monitored.

The type of cleanup technology employed to reduce contaminant levels to the groundwater standard is site-specific and will depend on a number of factors, including, but not limited to, the number and types of contaminants, contaminant properties, extent of contamination, hydrogeologic properties (soil and rock type) and cleanup goals. These factors, including the type of remediation employed at a site, will affect the time and cost to cleanup groundwater to the standard.[1,2,3,4]

One private company, Rhodia, Inc., was identified as impacted by the proposed 2L rules.

In its Rulemaking Petition, Rhodia states that it will save money if the new standard is adopted. A release of 1,1-dichloroethylene from an above ground storage tank in 1991 is the source of the site's 1,1-DCE groundwater contaminant plume. Division of Waste Management staff verified that this pollutant is the primary factor affecting assessment and cleanup costs at the Rhodia site (Appendix N).

Rhodia began operating a pump-and-treat groundwater remediation system at the site in September 1996. The primary objective of the groundwater extraction system is to hydraulically contain and control the movement of the groundwater contaminant plume to prevent further migration according to Rhodia's *2010 Annual Groundwater and Surface Water Sampling Results and 2010 Annual Groundwater Extraction System Performance Report*. The secondary objective is to reduce the concentration and mass of dissolved volatile organic contaminants, primarily 1,1-DCE, in the groundwater.

In 1996, 1,1-DCE groundwater concentrations were greater than 100,000 ug/L in wells near the source (132,000 ug/L in MW-16A and 161,000 ug/L in MW 17-B). In 2010, the concentrations were orders of magnitude lower in the same general area (830 ug/L in

[1] Cost Analyses for Selected Groundwater Cleanup Projects: Pump & Treat Systems and Permeable Reactive Barriers. USEPA OSWER EPA 542-R-00-013 February 2001 http://cluin.org/download/remed/542R00013.pdf
[2] Groundwater Cleanup: Overview of Operating Experience at 28 Sites. USEPA OSWER EPA 542-R-99-006 September 1999 http://www.epa.gov/tio/download/remed/ovopex.pdf
[3] A Citizens Guide to Pump & Treat: http://cluin.org/download/citizens/pump_and_treat.pdf
[4] A Citizens guide to Chemical Oxidation: http://cluin.org/download/citizens/oxidation.pdf

MW-16A and 3,800 ug/L in monitoring well 17-B), indicating that the pump-and-treat system has been effective in reducing the dissolved 1,1-DCE concentration in groundwater by more than 90 percent in approximately 15 years.

Rhodia asserts in its Petition that ten monitoring wells can be closed and monitoring costs saved if the 1,1-DCE standard is amended to 350 ug/L. Potential cost savings for Rhodia due to reduced monitoring are illustrated in the table below.

Table 2. Potential Cost Savings to Rhodia Due to Reduced Monitoring

	Number of wells that can be closed[a]	Estimated monitoring cost saving per year[b]
Rhodia, Incorporated 207 Telegraph Drive Gastonia, NC	10	$5,320

[a] The wells that can be closed are those where the 1,1-DCE groundwater concentration is less than 350 ug/L.

[b] Monitoring costs include the cost to sample the well (labor costs) and analyze the groundwater sample (analytical costs). Analytical costs were determined by multiplying the analytical cost per sample ($111) by the number of wells (10) that can be closed and the number of sampling events per year (2). The number of sampling events per year was based on Rhodia's current monitoring requirements. The analytical cost per sample was taken from Rhodia's Rulemaking Petition--$15,000 analytical cost/135 samples = $111. Example: $111 per sample x 10 wells x 2 sampling events per year = $2,220. The labor cost for well monitoring (maximum of $155 per well) was taken from the DWM UST Program's 2010 reasonable rate document at http://portal.ncdenr.org/web/wm/ust/rrd. Example: $155 per well x 10 wells x 2 sampling events per year = $3,100. Total monitoring costs per year = $2,220 + $3,100 = $5,320.

There are costs associated with closing monitoring wells in accordance with North Carolina regulations in Title 15A NCAC 02C .0113. The cost of a well closure is estimated to be $520 per well as determined by averaging the estimated cost provided by DWM staff ($584) and an independent consultant ($455). The one-time cost of properly closing the 10 wells, as required by NC regulations, is approximately $5,200.

Assuming 1,1-DCE concentrations will decrease another order of magnitude in the next 15 years, the estimated cost-savings to Rhodia over a fifteen-year period as a result of amending the groundwater standard from 7 ug/L to 350 ug/L due to reduced monitoring and operation and maintenance costs would be around $866,000. The full table is presented in Appendix L.

Table 3. Private Industry Costs and Benefits with the Proposed Rule Change

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**
Year Number	**0**	**1**	**2**	**3**	**4**
Costs					

Well Closure Costs		$5,304			
Total Costs	***$0***	***$5,304***	***$0***	***$0***	***$0***
Benefits					
Monitoring Cost Savings		$5,426	$5,535	$5,646	$5,759
Operation and Maintenance Costs					
Total Benefits	***$0***	***$5,426***	***$5,535***	***$5,646***	***$5,759***
Net Impact (benefits-costs)	**$0**	**$122**	**$5,535**	**$5,646**	**$5,759**
Total Impact (benefits+costs)	***$0***	***$10,730***	***$5,535***	***$5,646***	***$5,759***
30-year Net Present Value	**$866,145**				

Rhodia submitted a list of nine facilities, including the Rhodia site, known to have groundwater contamination above the current 1,1-DCE groundwater standard of 7 ug/L, as well as the number of monitoring wells at each site with contamination above the proposed 1,1-DCE standard of 350 ug/L. According to Rhodia, if 1,1-DCE is the only constituent exceeding a groundwater quality standard and the standard is changed from 7 ug/L to 350 ug/L, monitoring of 47 groundwater wells could cease. DWQ staff contacted the agency that regulates these sites to determine if 1,1-DCE is present above the current and proposed groundwater standard of 7 ug/L and 350 ug/L, respectively, and if 1,1-DCE is the only contaminant being remediated.

Based on information provided by DWM in Appendix N, 1,1-DCE contamination at the Rhodia site was the result of a 1,1-DCE storage tank release and was the sole motivation for the remediation. The company probably will be able to reduce the number of monitoring wells and the number of years needed for remediation. While 1,1-DCE was present at many of the other eight sites, other chlorinated solvents, such as tetrachoroethylene, trichloroethylene, 1,1,1-trichloroethane, commonly found in groundwater along with 1,1-DCE, were also present above the groundwater standard and are predicted to drive assessment and cleanup. It is unlikely that the assessment and cleanup costs for these sites will be reduced by a change in the 1,1-DCE standard.

For companies currently undertaking remediation activities, the cost to decommission an existing system and replace it with a different technology may likely be higher than any potential cost savings. For sites where groundwater contaminated with 1,1-DCE has not yet been discovered or remediation has not yet begun, the proposed standard may result in reduced assessment cost as the contaminant plume based on a standard of 350 ug/L will be less extensive than a contaminant plume based on a standard of 7 ug/L. In addition, a higher standard may give companies more flexibility in the type of remediation system used. Any future benefits resulting from changes in technology or remediation time resulting from this proposed rule change are contingent on the presence of other chemicals, selected technologies and other factors. DWQ does not attempt to estimate them in this analysis.

Public Benefits

The groundwater regulations in 15A NCAC 02L .0202(e) require the use of the following references, in order of preference, to be used in establishing groundwater standards:

1) U.S. EPA's Integrated Risk Information System (IRIS);
2) U.S. EPA Office of Drinking Water Health Advisories;
3) Other health risk assessment data published by U.S. EPA;
4) Other relevant, published health risk assessment data and scientifically valid peer-reviewed published toxicological data.

U.S. EPA's IRIS database provides high quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 550 chemical substances containing information on human health effects that may result from exposure to various substances in the environment.

No health-based benefits are expected as a result of changing the groundwater standard for 1,1-DCE from 7 ug/L to 350 ug/L because the proposed standard of 350 ug/L is based on the most recent U.S. EPA IRIS health effects data available at http://www.epa.gov/iris/subst/0039.htm. The current groundwater standard of 7 ug/L is based on the federal MCL which was calculated prior to the updated toxicity data being published. According to the U.S. EPA IRIS database, the chemical is less toxic than previously thought and is no longer considered a carcinogen by the oral route.

The revised language in .0202(d) and (f) would allow the EMC to eliminate the use of the federal MCL as a criterion for establishing a standard when the MCL is not based on the most recent EPA IRIS health effects data. Therefore, any future increase in a groundwater standard as a result of changes to .0202(d) and (f) will be supported by the use of the most recent health effects data and increased adverse health effects are not expected.

b. 15A 02L .0113-Variance (Option 3)

The variance rules in 15A 02L .0113 allow an applicant to request a variance to the 02L Groundwater Rules. Variance requests are submitted to the EMC for approval. Proposed revisions to the variance rules update the DWQ mailing address, allow the EMC to issue a statewide variance to the 02L rules and clarify the existing variance requirements. DWQ staff assumes that the benefits of this proposed option would essentially be the same as adopting Options 1 and 2. The inclusion of a statewide variance may reduce the number of future variances submitted to DENR because a statewide variance would apply to sites across the state. Staff time spent reviewing and processing a single statewide variance would likely be less than staff time spent reviewing multiple variances for the same request. The party requesting a variance, statewide or site-specific, will incur the cost of gathering the necessary data requirements.

Summary of Costs and Benefits

If Rhodia is the only company immediately affected by this rule change and no additional costs are placed on drinking water suppliers, the costs of this proposed rule change will be approximately $5,200. Benefits, in the form of less monitoring for NCDOT and Rhodia, will be around $9,100 in the first year and decrease slightly over time. Benefits, in the form of opportunity cost savings to NCDENR and operation and maintenance cost savings for Rhodia, will be around $222,000 in year sixteen and increase slightly over time. In the next 30 years, the net present value of the proposed rule change would be approximately $896,000. The risk analysis section examines additional costs and benefits that may be incurred by additional companies and wells or the need for more water remediation as a result of the rule change.

Table 4: Partial Representation of Total Costs and Benefits Associated with Proposed Rule Changes to 15A NCAC 02L .0202 Groundwater Quality Standards with Two Percent Inflation and Seven Percent Discount Rate

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**
Year Number	**0**	**1**	**2**	**3**	**4**
Costs					
Private Company Well Closure Costs	$0	$5,304	$0	$0	$0
Total Costs	***$0***	***$5,304***	***$0***	***$0***	***$0***
Benefits					
State Benefits					
DOT Reduced Monitoring	$0	$3,672	$3,537	$3,396	$3,247
DWM Opportunity Cost Savings					
Private Company Benefits					
Monitoring Cost Savings to Private Companies	$0	$5,426	$5,535	$5,646	$5,759
Operations and Maintenance Cost Savings		$0	$0	$0	$0
Total Benefits	***$0***	***$9,098***	***$9,072***	***$9,041***	***$9,006***
Net Impact (benefits-costs)	**$0**	**$3,794**	**$9,072**	**$9,041**	**$9,006**
Total Impact (benefits+costs)	***$0***	***$14,402***	***$9,072***	***$9,041***	***$9,006***
Net Present Value	**$895,775**				

IV. Risk Analysis

The proposed change to the groundwater standard for 1,1-DCE from 7 ug/L to 350 ug/L in 2L .0202 (g)(59) is responsible for the majority of benefits and costs. The benefit amount for private companies with releases of 1,1-DCE to groundwater hinges on whether or not 1,1-DCE is the only groundwater contaminant that will be responsible for requiring environmental cleanup which includes site characterization, installation of a treatment system, operation and maintenance of the treatment system and monitoring. A second possible risk is that 1,1-DCE pollution will affect a source of drinking water. This may create additional costs for public or private water systems.

While 1,1-DCE can be found in groundwater as a result of its direct release, as in Rhodia's case, it is commonly found as a breakdown product and in conjunction with other chlorinated solvents such as 1,1,1-trichloroethane, trichloroethylene and tetrachloroethylene (perchloroethylene). As noted in the previous section, none of the other companies cited by Rhodia has remediation projects that were motivated solely by 1,1-DCE contamination. Other more toxic breakdown products, such as vinyl chloride, are usually present as well. The chlorinated solvents and breakdown products listed are generally found in much higher concentrations and have more stringent groundwater standards than 1,1-DCE as illustrated below.

Table 5. Groundwater Standards for Chlorinated Solvents

<u>Contaminant</u>	<u>2L .0202(g) Groundwater Standard in ug/L</u>
1,1-Dichloroethylene	7 (350 proposed)
Tetrachloroethylene (or perchloroethylene)	0.7
1,1,1-Trichloroethane	200
Trichloroethylene	3
Vinyl Chloride	0.03

The presence of more toxic chlorinated solvents above their respective groundwater standard, and in much higher concentrations than 1,1-DCE, would likely trigger more complex and costly environmental cleanup efforts. If this is the case, then little or no benefits will be realized as a result of amending the groundwater standard for 1,1-DCE to 350 ug/L because it is not necessarily the pollutant of greatest concern.

The first analysis made the assumption that one company would benefit from the proposed rule change and that 1,1-DCE is the chemical motivating the cleanup effort. In addition to Rhodia, there could be current or future unidentified companies that have 1,1-DCE pollution that would benefit from the proposed rule change. Below is a sensitivity analysis to demonstrate the range of potential benefits for various combinations of the number of companies and the number of wells per company.

In addition to savings from well closures, some companies may benefit from reduced remediation times, which would lower maintenance and operations costs. There also would be cost savings to the DENR Division of Waste Management.

Table 6. Sensitivity Analysis of Net Benefits Based on Number of Companies and Number of Wells						
		Number of Wells				
		1	5	10	15	20
Number of Companies	1	$4,400	$21,800	$43,600	$65,400	$87,200
	2	$9,300	$46,100	$92,100	$138,100	$184,100
	3	$14,100	$70,300	$140,600	$210,800	$281,100
	4	$18,900	$94,500	$189,000	$283,500	$378,000
	5	$23,800	$118,800	$237,500	$356,200	$474,900

Impacts on Sources of Drinking Water

There are some very specific circumstances in which the standard change may affect groundwater sources that are used for drinking water and create costs for public drinking water treatment. This could happen if groundwater remediated to the new standard is used as a source of drinking water in the future or if a responsible party for the pollution cannot be identified. Each of these instances would be rare in the current environment. Usually an existing or new water company would avoid using a contaminated source of water or would only use one if they believed treatment would be cost effective (benefits greater than costs). DENR knows of no local government that had to bear the cost of additional water treatment from 1,1-DCE pollution because responsible parties are usually identified. We present this analysis to better describe potentially impacted parties and to give a rough estimate of the costs associated with 1,1-DCE contamination to a source water.

Public water systems are defined as those which provide piped drinking water to at least 15 connections or 25 or more people sixty or more days per year. They are further characterized as Community Water Systems, Non-Transient Non-community Water Systems and Transient Non-Community Water Systems as follows:

A "Community Water System" (CWS) means a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

A "Non-Transient Non-Community Water System" (NTNCWS) means a public water system that regularly serves at least 25 of the same nonresident persons per day for more than six months per year. Examples of such systems are those serving the same individuals (industrial workers, school children, church members) by means of a separate system.

A "Transient Non-Community Water System" (TNCWS) means a non-community public water system that does not serve 25 of the same nonresident persons per day for more than six months per year. Examples of such systems are those, RV park, diner or convenience store where the permanent nonresident staff number less than 25, but the number of people served exceeds 25.

Any of these systems could be adversely affected if 1,1-DCE is detected in their source water above 7 ug/L; however, the MCL and surveillance monitoring requirements only apply to Community and Nontransient Non-community systems. According to the DENR Public Water Supply Section (PWS Section), as of September 29, 2011, there are 2,081 Community and 406 Non-transient Non-community active public water systems in North Carolina where groundwater is source water. The systems are further classified below as state, local, federal or private, along with the population served.

Table 7. Classification and Number of Public Water Systems

Ownership Type	Community	Nontransient Non-community	Total	Population Served
Federal	8	8	16	158,484
Local	549	141	690	6,676,495
State	3	14	17	945
Private	1,520	243	1,763	877,798
Total	*2,081*	*406*	*2,487*	*7,713,722*

Violations of the 1,1-DCE drinking water standard are not common. The PWS Section anticipates that if the groundwater protection standard for 1,1-DCE were raised from 7 to 350 ug/L, the total number of additional system affected would be small, perhaps one facility every ten years, as would the corresponding increase in workload for staff. Additional activities and cost associated with compliance, monitoring, document review, approvals, inspections and technical assistance were determined to be *deminimus* relative to the overall workload that currently exists.

According to the PWS Section, only three active systems have been in violation of the state and federal drinking water standard for 1,1-DCE since 2001. These systems are identified in Table below.

Table 8. Public Water Supply Systems Found in Violation of the 1,1-DCE MCL

PWS System	System Type	County	Treatment Type	Year of Last Violation
Harbor House	Private Community	Mecklenburg	Carbon Filter	2009
American Truetzschler	Private NTNC*	Mecklenburg	Carbon Filter	2005
Middlesex Water System	Local Community	Nash	In process of installing treatment system	2011

*Non-Transient Non-Community Water System

According to the PWS Section, the best available treatment technology for 1,1-DCE is a granular activated carbon filter system. Cost information was requested from the three facilities that have implemented or investigated this technology (Harbor House, American Truetzschler, Middlesex), however, no response was received after numerous requests via email and phone.

The PWS Section referenced a 1989 Calgon Carbon Corporation publication (http://www.calgoncarbon.com/documents/UseofGroundwater.pdf) that estimates a total capital expenditure of approximately $125,000 for a complete 300 gpm (gallons per minute) treatment system (which is an average size system). In the table below, information from this publication was used, after adjusting for inflation from 1989 to 2011 (http://www.bls.gov/data/inflation_calculator.htm), to estimate the cost of compliance for a typical water supply system regulated under the NC Drinking Water rules and found to be in violation of the 1,1-DCE maximum contaminant level (MCL). Since this estimate was done some time ago, it likely overstates the actual cost because pollution control technology tends to fall in price over time. Compliance costs for a period of five years are illustrated below. The full table is presented in Appendix M. Potential costs to come into compliance include the following:

- Installation of a granular activated carbon treatment system;
- Annual operation and maintenance (O&M) of the system;
- Quarterly monitoring.

Table 9. Estimated Compliance Cost for Public Water Supply Systems with a 1,1-DCE Violation

Fiscal Year	**2021-22**	**2022-23**	**2023-24**	**2024-25**	**2025-26**
Year Number	**10**	**11**	**12**	**13**	**14**
Costs					
Estimated Capital Expenditure	$276,468	$0	$0	$0	$0
Annual Operation & Maintenance	$93,497	$95,367	$97,274	$99,220	$101,204
Annual Monitoring	$731	$746	$761	$776	$792
Total Costs	***$370,696***	***$96,113***	***$98,035***	***$99,996***	***$101,996***

[1]Capitol expenditure is a one-time cost estimated using the estimated cost of installing a typical (accepted standard size) granular activated carbon treatment system ($125,000) from the 1989 Calgon publication "Use of Carbon Absorption Processes in Groundwater Treatment" (http://www.calgoncarbon.com/documents/UseofGroundwater.pdf) and adjusted for inflation (1989-2011) and rounded to the nearest hundred ($276,468).
[2]The annual operation and maintenance costs were taken from the 1989 Calgon publication ($42,000), adjusted for inflation (1989-2011), and rounded to the nearest hundred ($93,497).
[3]The cost of monitoring is estimated to be $150 per sample by the NC Public Water Supply Section. A minimum of one sample per quarter ($600/year) will be required.
Table is adjusted for two-percent inflation.

Assumptions:

- If the 1,1-DCE groundwater standard is 350 ug/L and the maximum contaminant level for drinking water is 7 ug/L, then every ten years one Community or Nontransient Non-community public water supply system that uses groundwater as source water will have a 1,1-DCE MCL violation and will be required to take corrective action. This assumption is based on NC and USEPA 1,1-DCE MCL violation occurrence data.The first violation will occur in 2021, ten years after the groundwater standard is changed to 350 ug/L.
- A public water supply using groundwater as source water that is in violation of the 1,1-DCE MCL will be able to meet the MCL by installing the standard size carbon filter system described in the 1989 Calgon publication.
- The carbon system will be effective in reducing a 1,1-DCE groundwater concentration of 350 ug/L to 7 ug/L or less.
- The activated carbon will be replaced no more than once a year.
- The system will be monitored quarterly to determine compliance and to ensure the carbon system is working properly.
- Annual operation and maintenance costs will begin one year after the carbon filter system is installed.

Based on the information provided by the PWS Section, approximately 71 percent of the potentially impacted water systems are privately owned. Another 28 percent of the systems are owned and operated by local government. The state and federal governments each own and operate less than one percent of all facilities. Below is a breakdown of the estimated total yearly costs that are attributed to private companies and local governments based on the percent of total population served (or impacted water systems). The cost to Federal and State systems is negligible.

Table 10. Breakdown of Total Yearly Costs to Public Water Supply Systems

System Type	Ownership Percentage[1]	2021-22	2022-23	2023-24	2024-25	2025-26
Private	71%	$263,194	$68,240	$69,605	$70,997	$72,417
Local	28%	$103,795	$26,911	$27,450	$27,999	$28,559
Federal*	0.50%	$1,853	$481	$490	$500	$510
State*	0.50%	$1,853	$481	$490	$500	$

[1] Ownership percentage was determined as follows: The number of systems per ownership type was divided by the total number of systems. For example, for private systems the ownership percentage was determined by dividing the number of private systems (1,763) by the total number of systems (2,487) = 0.71 or 71%.

To determine yearly cost distribution the total annual costs were multiplied by the system type ownership percentage. For example, the 2021-22 cost distribution for private systems was determined by multiplying 0.71 (71%) by the total annual cost ($370,696) = $263,194.

*The costs to Federal and State systems are considered to be negligible.

Other Issues

There are limitations to the type of information that can be obtained to develop fiscal and economic impacts. The following are important factors to consider in estimating costs and benefits:

- Incident response databases at state agencies may not contain enough information to be useful in this analysis about the status of sites, types of substances that need to be cleaned up, and cleanup technology used. Readily available data may not show detailed information on which substances appear at what sites. Most databases do not tell us if a site is cleaning groundwater with pump-and-treat or some other technology. General information about the type of release is shown in most databases. There is little consistency between state regulatory agencies with respect to the types of information collected.
- The actual duration of a groundwater cleanup varies based on many factors. The concentration of substances, vertical and lateral extent of contamination, solubility of substances, the ability of the substance to naturally degrade or attenuate, the type of cleanup technology employed and the potential threat to groundwater and health all play a role in determining the time needed to cleanup a site. The best information available is from the Underground Storage Tank Section and shows that most pump-and-treat groundwater cleanups will take approximately 10 to 15 years, although many of these sites may never meet the 15A NCAC 02L .0202 groundwater quality standards. Because the duration of cleanup varies, the overall cost/benefit for cleanup will vary from site to site.
- Raising a standard could result in a decrease in the number of years that a pump-and-treat cleanup operation is in place where a cleanup currently is underway. Therefore, the change could affect the overall cost of cleanup. There is no standard baseline data for the cost of cleaning up specific substances. The assessment of contamination and the duration of cleanup are the most significant factor in determining costs.

V. <u>Alternative Policies</u>

The proposed rulemaking to change the 1,1-DCE groundwater standard from 7 ug/L to 350 ug/L is the result of a rulemaking petition submitted by Rhodia, Incorporated. The health effects data in the U.S. EPA IRIS database has been updated and a revised health-based groundwater standard of 350 ug/L is considered a viable option to the current standard. The proposed standard of 350 ug/L will incorporate the most recent health effects data as published in the U.S. EPA IRIS database.

One alternative considered by DWQ was to leave the 1,1-DCE groundwater standard at 7 ug/L because the federal maximum contaminant level is 7 ug/L and is a regulatory criterion used to establish groundwater standards in 15A NCAC 02L .0202(d). However, the federal maximum contaminant level is not based on the updated health effects data in U.S. EPA's IRIS database; therefore, this alternative was not considered a viable option. Additional rule language is proposed in 2L .0202(d) and (f) to ensure that the Environmental Management Commission can establish a groundwater standard using the most recent U.S. EPA IRIS health effects data.

Another alternative, recommended by the NC Division of Public Health, State Toxicologist, Ken Rudo, was to change the 1,1-DCE standard to 35 ug/L based on the updated health effects data in the U.S. EPA IRIS database and a safety factor of 10 to account for its potential carcinogenicity. While the IRIS database lists 1,1-DCE as a Class C, potential human carcinogen, U.S. EPA has determined that data are inadequate for an assessment of human carcinogenic potential for the oral route, which includes drinking water. Therefore, this alternative was not considered a viable option.

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March 14, 2011

Ms. Coleen Sullins
Director
NC Division of Water Quality
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Re: Rhodia Inc. – Petition for Rule-making, 15A N.C.A.C. 2L .0202(g)(59), Amendment to Groundwater Quality Standard for 1,1-Dichloroethylene

Dear Ms. Sullins:

On behalf of Rhodia Inc. (Rhodia), we are, by this letter, filing this Petition for Rule-Making (the "Petition") pursuant to and in accordance with N.C.G.S. § 150B-20 and 15A N.C.A.C. 2I .0501, which allow any person to petition the Director of the appropriate Division of the North Carolina Department of Environment and Natural Resources to adopt, amend or repeal an existing rule by submitting a rule-making petition. Specifically, Rhodia is seeking to amend the groundwater quality standard for 1,1-dichloroethylene ("1,1-DCE") as set forth at 15A N.C.A.C. 2L .0202(g)(59). Pursuant to 15A N.C.A.C. 2I.0501(a), we are addressing this Petition to you as the Director of the North Carolina Division of Water Quality ("DWQ") since DWQ (and specifically within DWQ, the Classification and Standards Unit of the Planning Section) is the Division responsible for developing and implementing groundwater quality standards as required by applicable law and regulations, including but not limited to 15A N.C.A.C. 2L .0202(d) and (e). As the petition and supporting documents exceed 10 pages in length, we are providing 20 copies of the whole petition and its attachments as required by 15A N.C.A.C. 2I.0501(c).

In the following sections, we provide the information that corresponds to the requirements for a rule-making petition as set forth in subparagraphs to 15A N.C.A.C. 2I .0501(b). For ease of reference, we have set forth in bold, italicized type the required information required by each subparagraph followed by the requisite information.

(1) ***Provide the text of the proposed rule(s) conforming to the Codifier of Rules' requirements for publication of proposed rules in the North Carolina Register.***

The current groundwater quality standard for 1,1-dichloroethylene (in micrograms per liter) in 15A N.C.A.C. 2L .0202(g)(59) is:

(59) 1,1-Dichloroethylene (vinylidene chloride): 7

Rhodia requests that the groundwater quality standard for 1,1-dichloroethylene in 15A N.C.A.C. 2L .0202(g)(59) be amended to state:

(59) 1,1-Dichloroethylene (vinylidene chloride): ~~7~~ 350

(2) ***Provide the statutory authority for the agency to promulgate the rule(s).***

The statutory authority for the agency to promulgate the rule is N.C.G.S. § 143-214.1 and N.C.G.S. § 143B-282(a)(2).

(3) ***Provide a statement of the reasons for adoption of the proposed rule(s).***

U.S EPA's Determination that the Risks Posed by 1,1-DCE Have Been Overstated

Historically, the groundwater quality standard for 1,1-DCE has been 7μg/L, the same as the maximum contaminant level ("MCL") under the Federal Safe Drinking Water Act.

In the July 18, 2003 Federal Register, the United States Environmental Protection Agency ("U.S. EPA") published its review of existing drinking water standards for 15 different compounds, including 1,1-DCE. Based on this review, which included a revision to the file for 1,1-DCE in the Integrated Risk Information System ("IRIS"), U.S. EPA concluded that the risks previously cited for 1,1-DCE had been greatly overstated. Although the health effects data supported the calculation of a less stringent standard for 1,1-DCE, U.S. EPA decided not to change the MCL for totally non-scientific reasons – competing workload priorities, the administrative costs associated with a required rulemaking, and the burden on states and the regulated community to implement any regulatory change that resulted. A copy of the U.S. EPA notice from the July 18, 2003 Federal Register is attached as Exhibit A.

Since then, U.S. EPA has on two occasions – October 28, 2003 and June 22, 2005 – had the opportunity to review the IRIS standard for 1,1-DCE again. In each instance, U.S. EPA reaffirmed its previous conclusion that the health risks posed by 1,1-DCE had been overstated. (See Section VII. of U.S. EPA's current IRIS file for 1,1-DCE attached as Exhibit B.)

North Carolina Regulations Governing the Establishment of Groundwater Quality Standards

Two regulations govern the establishment of groundwater quality standards in North Carolina. First, under 15A N.C.A.C. 2L.0202(d), the lesser of six different standards is to be used to set a compound's groundwater limit. Second, 15A N.C.A.C. 2L.0202(e) requires the Environmental Management Commission ("EMC") and the North Carolina Department of Environment and Natural Resources ("NCDENR") to establish groundwater standards based upon four sources of toxicity data listed "in order of preference" in the regulation. (To avoid lengthy regulatory citations, these rules will be referred to as 202(d) and 202(e) throughout the remainder of this Petition.)

Subparagraphs 202(d) and 202(e) are expressly inter-related. They must be read in tandem because the sources of toxicity data for establishing standards listed in 202(e) must "*correspond to levels described in Paragraph (d) of this Rule*". (Emphasis added.) From this it follows that if a basis for a groundwater quality standard listed in 202(d) does not "correspond" to an accepted reference source listed in 202(e), then the standard in 202(d) cannot be used. (Copies of these two regulations are attached as Exhibit C.)

Why 202(d) and 202(e) Require that Groundwater Quality Standard for 1,1-DCE Must Be Changed from 7mg/L to 350mg/L.

202(e) states that the "following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in" 202(d):

1. Integrated Risk Information System (U.S. EPA).

2. Health Advisories (U.S. EPA Office of Drinking Water).

3. Other health risk assessment data published by U.S. EPA.

4. Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.

202(d) provides that groundwater quality standards are to be established as the least of the following for a compound:

1. Systemic threshold concentration;

2. Concentration corresponding to a 1×10^{-6} incremental lifetime cancer risk;

3. Taste threshold limit value;

4. Odor threshold limit value;

5. Maximum contaminant level; or

6. National secondary drinking water standard.

1,1-DCE does not have a taste threshold limit value, odor threshold limit value or national secondary drinking water standard. In its IRIS revisions, U.S. EPA removed the oral cancer slope factor for 1,1-DCE and concluded that the compound was only a possible human carcinogen. As a result, there is no cancer risk concentration that can be used to establish a groundwater quality standard.

Although the "least" of the six identified standards in 202(d) is the MCL of 7 µg/L, it legally cannot be used in this situation. The Federal Safe Drinking Water Act requires that determination of an MCL for a compound must be based in part on the oral reference dose (RfD) for that compound. In its IRIS re-evaluation of 1,1-DCE in 2003, U.S. EPA recalculated the RfD for 1,1-DCE, changing it from 0.009 mg/kg/day to 0.050 mg/kg/day. As cited above, pursuant to 202(e), IRIS is the most preferred reference source for the establishment of groundwater quality standards. However, even though it changed the RfD, U.S. EPA did not change the MCL for 1,1-DCE. Consequently, the MCL for 1,1-DCE no longer "corresponds" to the IRIS evaluation of 1,1-DCE. **<u>As a result, under North Carolina regulations, the current MCL legally cannot be used to establish the 2L groundwater quality standard for 1,1-DCE.</u>**

The only basis for establishing a groundwater quality standard for 1,1-DCE is the systemic threshold concentration for 1,1-DCE. According to 202(d)(1), the systemic threshold concentration is calculated as follows:

> [Reference dose mg/kg/day x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganic; .20 for organics)] / [2 liters/day (avg. water consumption)]

Since this formula can use U.S. EPA's recalculated RfD for 1,1-DCE, the systemic threshold concentration "corresponds" with IRIS and thus complies with the requirements of 202(e). Performing the calculation using the recalculated RfD of 0.050 and a relative source contribution of .20 (as 1,1-DCE is an organic compound), the systemic threshold concentration for 1,1-DCE is 350 µg/L, 50 times higher than the current 2L standard.

Based on the express language of 202(d) and (e), the proposed rule amendment must be approved.

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Rhodia's Prior Requests for Changing the Standard for 1,1-DCE

2005 Triennial Review

During the two most recent triennial reviews of groundwater quality standards conducted by DWQ as required by 15A NCAC 2L .0202(f), Rhodia has submitted written public comments requesting that the EMC change the groundwater quality standard for 1,1-DCE. Rhodia first submitted public comments in a letter to David Hance of the Division of Water Quality dated September 28, 2004. (A copy of this letter is attached as Exhibit D.) Based on U.S. EPA's 2003 conclusions that the risks from 1,1-DCE had been overstated and an analysis of North Carolina's regulations governing the establishment of groundwater quality standards, Rhodia concluded that the 2L standard for 1,1-DCE should be changed from 7 μg/L to at least 322 μg/L. Similar comments were also independently submitted by Dr. Shawn L. Sager, a principal scientist with ARCADIS G&M of North Carolina, Inc., in a letter dated September 13, 2004. (A copy of this letter is included as Exhibit E.) These letters were reviewed by Dr. Luanne K. Williams, a toxicologist with the Occupational Environmental Epidemiology Branch of the North Carolina Division of Public Health. **In comments enclosed with a letter dated October 1, 2004, Dr. Williams, the State's toxicologist, concluded that based upon the information provided in Rhodia's public comments, "*the recommended groundwater quality standard for 1,1-dichloroethylene is 350 μg/L and not 7 μg/L.*"** (Emphasis added.) (A copy of Dr. Williams' letter is attached as Exhibit F.)

The hearing officers did not dispute the arguments presented by Rhodia and Dr. Sager in their public comments or the conclusion of Dr. Williams, the State's toxicologist. Nevertheless, the 2004 hearing officers' report concluded that they were legally prevented from changing the standard for 1,1-DCE. The hearing officers stated that in order for the 1,1-DCE standard to be changed, the groundwater quality regulations in 15 N.C.A.C. Subchapter 2L would have to be amended. The hearing officers, however, did not provide any specifics as to what amendments were required.

In response to the hearing officers' conclusions, Rhodia took its arguments directly to the EMC. In a January 18, 2005 letter to Dr. David H. Moreau, then chairman of the EMC, Rhodia explained why the EMC was required to change the standard for 1,1-DCE. (A copy of that letter is attached as Exhibit G.) However, at its February 2005 meeting, the EMC refused to do so.

2009 Triennial Review

In a letter dated May 28, 2009, Rhodia (this time joined by Radiator Specialty Company and Ashland Inc.) again requested that the groundwater quality standard for 1,1-DCE be changed from 7 μg/L to 350 μg/L as part of the 2009 triennial review. (A copy of this letter is attached as Exhibit H.) In addition to the reasons set forth in 2004, Rhodia noted that in a December 31, 2003 rulemaking, U.S. EPA had relied on the IRIS revisions to change the recommended surface water quality standard for 1,1-DCE from 0.057 µg/L to 330 µg/L, an increase of nearly 6,000 times the previous standard.

The hearing officers' report, dated September 10, 2009, was nearly identical to the report of the hearing officers in 2004. Once again, the hearing officers did not disagree with Rhodia's contentions or conclusions. However, once again, despite that lack of disagreement, the hearing officers did not change the standard for 1,1-DCE. Rather, the hearing officers' report referenced the work of a Groundwater Stakeholder Work Group that had met between July 14 and December 1, 2005 which "discussed needed changes to the groundwater rules to update groundwater standards so that the most up-to-date toxicity information was being incorporated." However, apparently due to the fact that no such regulatory changes had been made, "the EMC Groundwater Committee decided not to propose any changes to the groundwater rules stating that the 1,1-DCE issue could be dealt with using the variance process." (A copy of the portion of the Hearing Officers' report relating to Rhodia's comments is attached as Exhibit I.) At its September 2009 meeting, the EMC did not change the standard for 1,1-DCE.

Rhodia's Variance Request

Pursuant to the Groundwater Committee's conclusion "that the 1,1-DCE issue could be dealt with through the variance process" and in fulfillment of its legal obligation to exhaust its administrative remedies, on November 1, 2010, Rhodia filed with the EMC an *Application for a Variance to the 2L Groundwater Quality Standard for 1,1-Dichloroethylene (1,1-DCE)*.

N.C.G.S. §143-215.3(c) provides the statutory authority to grant variances, which authority is implemented by regulation at 15A NCAC 2L .0113. Pursuant to these authorities, an applicant for a variance must show (1) that the variance will not endanger human health or safety and (2) that compliance with the existing standard "cannot be achieved by application of the best available technology found to be economically reasonable . . . and would produce serious hardship without equal or greater benefits to the public." (N.C.G.S. §143-215.3(e)(2)) Rhodia pointed out that the first factor was satisfied for the reasons previously stated in this Petition, namely that based on U.S. EPA's revisions to its IRIS evaluation as applied to North Carolina regulations governing the establishment of groundwater quality standards, a standard of 350mg/L for 1,1-DCE in groundwater would be protective of public health and the environment, a conclusion with which the State's toxicologist and NCDENR staff responsible for the triennial review agreed.

As to the second factor, Rhodia contended that it was not applicable to or determinative of the variance request as Rhodia was not basing the request on the grounds that compliance with the 1,1-DCE standard was technically infeasible or would cause undue economic hardship but rather on the fact that the current standard for 1,1-DCE was wrong.

Although the establishment of groundwater quality standards based on North Carolina regulations is the responsibility of the Classification and Standards Unit of DWQ's Planning Section, the EMC forwarded the variance application to the Division of Waste Management ("DWM") as DWM has jurisdiction over Rhodia's cleanup activities at a site in Gastonia, North Carolina.[1] DWM has advised Rhodia it could not proceed with the variance request for a number of site specific reasons, none of which are in any way relevant to Rhodia's central allegation that the standard is simply wrong as a matter of law and should not apply either at Rhodia's site or throughout the State of North Carolina. For clarity, Rhodia's Petition and rationale for this change in the groundwater standard is not based upon and has nothing whatsoever to do with any site specific issues or conditions at the Gastonia site that has been undergoing remediation for 13 years and running.

Over the past six plus years, Rhodia has submitted public comments as part of the triennial reviews and, at the direction of EMC, a variance application. None of these actions has resulted in the legally required change to the groundwater quality standard for 1,1-DCE, either statewide or as applied to Rhodia. Rhodia's only remaining administrative remedy is to submit this Petition for Rulemaking.

(4) *Provide a statement of the effect on existing rules or orders.*

Other than the rule to be amended, Rhodia is not aware of any effect on existing rules or orders.

(5) *Provide copies of any documents and data supporting the proposed rule(s).*

We have attached copies of documents supporting the proposed rule as Exhibits A through J.

(6) *Provide a statement of the effect of the proposed rule(s) on existing practices in the area involved, including cost factors for persons affected by the proposed rule(s).*

This rule would apply to sites with known groundwater contamination where the level of 1,1-DCE exceeds the current standard of 7 μg/L and sites where in the future groundwater contaminated by 1,1-DCE might occur or be discovered. The effects on these sites would be as follows:

[1] Since 1997, a groundwater remediation system has been operating to remediate groundwater contamination at a specialty chemical manufacturing facility located at 207 Telegraph Drive in Gastonia, North Carolina (the "Site") formerly owned and operated by Rhone-Poulenc Inc. Since January 1, 1998, Rhodia has been contractually obligated to perform this clean up. The primary contaminant of concern is 1,1-DCE.

The Area of 1,1-DCE Contamination Above State Standards Will Either Decrease or Cease to Exist Altogether.

The highest concentrations of contamination always exist at what is known as the source area, such as where a spill occurred or a tank leaked. As contamination migrates out from the source area in the groundwater, the concentration decreases as the contaminants are dispersed in the groundwater or as they start to break down due to the effect of natural conditions.

Under North Carolina law and regulations, the area where groundwater is considered contaminated is the area where the concentrations exceed the 2L standard. For a site with 1,1-DCE contamination, this currently is the area where the level of 1,1-DCE exceeds 7 μg/L. Based on the principle described in the preceding paragraph, it follows that the point where the concentration is 7 μg/L will be further from the source area than the point where the contamination is 350 μg/L. As a result, if the standard is changed to 350 μg/L, the area of contamination at all sites with 1,1-DCE in the groundwater will either be smaller or no longer exist.

Groundwater Investigation Costs Will Decrease

Under North Carolina law and regulations, a party responsible for groundwater contamination at a site must determine the vertical and horizontal extent of contamination, that is how far out the contamination extends and how deep it goes. As to 1,1-DCE, under the current standard, a party must continue to install wells until the levels are below 7 μg/L. If the standard is changed to 350 μg/L, the area of contamination will not be as large and it will take fewer wells and groundwater samples to determine the boundaries of the contamination. A smaller number of wells and groundwater samples will obviously decrease the cost of the overall investigation. These cost savings will apply to ongoing investigations which have not yet been completed and any investigations conducted in the future.

Groundwater Monitoring Costs Will Decrease

As part of groundwater remediation efforts, responsible parties periodically must sample permanent monitoring wells in the area of contamination to determine how the clean up is proceeding and when the 2L standards have been met and the clean up is done. Once a well is shown to meet the 2L standards consistently, monitoring of it is no longer required.

Parties remediating groundwater contaminated with 1,1-DCE currently have to sample any monitoring well where the concentration of 1,1-DCE exceeds 7 μg/L. Whether a clean up is being done by an active remediation system (such as a pump-and-treat, air sparging or soil vapor extraction system) or by a process of monitored natural attenuation, levels of 1,1-DCE in groundwater will reach 350 μg/L before reaching 7 μg/L. From this it follows that fewer monitoring wells will have to be sampled for a shorter period of time and can be taken out of service sooner if the groundwater quality standard for 1,1-DCE is 350 μg/L instead of 7 μg/L.

There are numerous sites in North Carolina where the concentration of 1,1-DCE exceeds the current groundwater quality standard of 7 μg/L. These include sites regulated under the Resource Conservation and Recovery Act, the Inactive Hazardous Sites Act, the Comprehensive Environmental Response, Compensation and Liability Act and the Dry-Cleaning Solvent Cleanup Act. The following table is a list of sites Rhodia's undersigned counsel is currently aware of where the level of 1,1-DCE in groundwater exceeds the current standard of 7 μg/L and what the compliance status of each site would be if the standard was 350 μg/L.

Name and Address of Site	*Number of Monitoring Wells > 7 μg/L*	*Number of Monitoring Wells > 350 μg/L*
Rhodia Inc. 207 Telegraph Drive Gastonia, NC	21	11
Radiator Specialty Company 100 Radiator Road Indian Trail, NC	9	1
Suttle Avenue, LLC Intersection of Wilkinson Blvd and Suttle Ave. Charlotte, NC	1	0
Intersection of Pearson's Turnpike and Chicksaw Road Gastonia Township, NC	8	0
The Park Ministries, Inc. 2500 Independence Blvd. Charlotte, NC	1	0

Design Center Carolinas, LLC 118-120 West Worthington Ave. Charlotte, NC	1	0
Intersection of Highway 321 and Rankin Lake Road Gastonia, NC	3	0
Former Ashland Inc. Site 1415 South Bloodworth Street Raleigh, NC	11	1
Former Ashland Inc. Site 2802 Patterson Street Greensboro, NC	11	6
TOTAL NUMBER OF WELLS	***66***	***19***

Assuming that 1,1-DCE is the only constituent exceeding a groundwater quality standard in these wells, if the standard is changed from 7 μg/L to 350 μg/L, monitoring of 47 groundwater monitoring wells across all of these sites can likely cease and the wells can be abandoned.

More Remediation Technologies Can Potentially Be Used

There are two predominant geologic features in North Carolina that affect the remediation of contaminants like 1,1-DCE. First, the groundwater aquifer is unconfined meaning that water exists from shallow to deep depths without interruption by any confining layer. Second, the crystalline bedrock is fractured with any number of fissures and cracks running through it in sizes and directions that are not capable of precise determination. As a result, when a contaminant that is heavier than water like 1,1-DCE reaches the groundwater, it moves vertically through the water table eventually reaching the fractures in the crystalline bedrock. If a sufficient amount of a contaminant is released, what eventually collects in the bedrock is what is called a dense non-aqueous phase liquid or DNAPL which is a liquid that is not only denser than water but also does not dissolve readily in water. This geologic setting exists throughout the entirety of the Piedmont region.

There are a number of existing and emerging remedial technologies that theoretically can remediate 1,1-DCE in groundwater. Exhibit J summarizes the remedial technologies that have been considered for implementation at the Rhodia site.

Industry experience over approximately the last two decades has shown that attempts to remediate sites with relatively small DNAPL source areas (typically less than one acre) using the technologies described on Exhibit J, even under ideal hydrogeologic and site conditions, are typically only able to achieve about a one order of magnitude reduction in contaminant concentration (which is equal to a 90% reduction.)[2] For example, if the level of contamination is 1,000 μg/L, these technologies will only be able to reduce the contamination to 100 μg/L.

With the current standard of 7 μg/L, if maximum level of contamination is 70 μg/L or less, the use of these technologies is viable as the groundwater quality standard can likely be achieved and the remediation completed. On the other hand, if the

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[2] GeoSyntec. 2004. *Assessing the Feasibility of DNAPL Source Zone Remediation: Review of Case Studies.* Prepared by GeoSyntec Consultants. Prepared for Naval Facilities Engineering Services Center, Port Hueneme, California. (Performed a technical survey of DNAPL technology performance at 175 sites. Most respondents (vendors, users, and regulators) reported that remediation resulted in greater than 80% DNAPL mass removal. The results from this study were obtained by asking site personnel to report the mass removal that was achieved by each project, and was not an independent review of site data. The previous studies were based on mining monitoring data from sites and performing an independent analysis of treatment technology performance. Despite the different approaches, the GeoSyntec survey and the two data mining projects reached the similar conclusion that source zone remediation resulted in about a one-order-of-magnitude or 90% reduction in initial concentration.)

Kingston, J.L.T. 2008. "A Critical Evaluation of In-Situ Thermal Technologies." PhD Dissertation, Arizona State University, May. (Conducted a review of 182 sites where thermal technologies were used for source treatment and identified 14 sites with sufficient performance data to evaluate the impact of source treatment on groundwater concentration and mass discharge. For nine of these 14 sites, the thermal treatment resulted in 90% or less reduction in contaminants of concern concentrations in groundwater compared to pre-treatment conditions.)

Lebron, C., D. Major, and B. Kueper, 2008. "DNAPL Technology Evaluation Screening Tool (DNAPL TEST)," Version Beta1.0 2008-02-15. Developed by Geosyntec Consultants, NFESC, Queen's University, and University of Edinburgh. Developed for U.S. Department of Defense Environmental Security Technology Certification Program (ESTCP), Project ER-0424. (Reported groundwater chlorinated volatile organic compound (CVOC) concentration reductions for 72 DNAPL remediation projects. The median percent reduction in concentration achieved for all projects was 92%. Individual technologies were reported as having the following median concentration reductions due to treatment: bioremediation, 95% (n = 17); chemical oxidation, 91% (n = 40); and thermal, 96% (n = 13). Nine projects (13%) reported an increase in groundwater concentrations following DNAPL treatment. The study also reported DNAPL mass removal for 90 remediation projects. The median DNAPL mass removal achieved for all projects was 71%. Only thermal technologies using electrical resistive heating or steam were reported to have median DNAPL removal above 90%.)

McGuire, T.M., J.M. McDade, and C.J. Newell. 2006. "Performance of DNAPL Source Depletion Technologies at 59 Chlorinated Solvent-Impacted Sites," *Ground Water Monitoring and Remediation*, 26(1), 73-84. (Analyzed groundwater concentration data at 59 sites where DNAPL remediation had been performed using one of the four commonly applied technologies: enhanced bioremediation, in situ chemical oxidation, thermal treatment, and surfactant flushing. For these 59 sites, the median treatment volume was small, equivalent to 100 feet by 100 feet in area (<0.25 acres) and 10 feet thick (~3,800 cubic yards). The median distance between the treatment point (an injection well or thermal point) and the monitoring well where the data were collected was 7 feet. For these 59 sites, remediation performance was assessed by calculating the change (i.e., percent decrease or increase) in groundwater concentrations within the treatment zone from before treatment and after treatment was completed. Results indicated that the median percent reduction in parent CVOC concentrations due to treatment was 92%. The median reduction in parent CVOC concentrations by technology was: bioremediation, 95% (n = 26); chemical oxidation, 88% (n = 23); thermal, 97% (n = 6), and surfactant/cosolvent, 95% (n = 4).)

maximum contaminant level is, for example, 3,500 μg/L, the most these technologies can typically do is to reduce the level of contamination to 350 μg/L, still far above the level needed to obtain a determination that no further clean up is required. In that situation, since the remediation will still continue for a number of years, the most cost effective and feasible option is often a system that will contain the area of contamination and gradually reduce the levels over time, like a pump-an-treat system.

However, if the groundwater quality standard is 350 μg/L, then the use of other clean up technologies becomes viable at sites with much higher levels of contamination, as the likelihood of completing the clean up to the standard in a much shorter period of time greatly increases. This would achieve more clean up of the environment quicker than the current standard of 7 μg/L will ever provide.

As a result, if the proposed rule amendment occurs, at all sites with 1,1-DCE contamination, a further review of alternate remedial technologies will be appropriate and may show that, because the plume is smaller and the standard is higher, some technologies have become more feasible and cost effective. Even if that review shows that other technologies are still not feasible or cost-effective, the current remediation system, whether it be pump-and-treat system or something else, will not have to be operated for as long a period of time to reach a 350 μg/L standard as compared to a 7 μg/L standard.

(7) ***Provide a statement explaining the computation of the costs factors.***

At a site with 1,1-DCE groundwater contamination, two categories of costs will be incurred. The first includes all costs to assess and determine the vertical and horizontal extent of the contamination. This category will consist of costs to install and sample groundwater monitoring wells and evaluate the results of such sampling. The second category includes all costs to identify and evaluate viable technologies to remediate the contamination and then perform the clean up with the selected technology. This category will consist of consulting, engineering, construction, and operation and maintenance costs.

Figure 1 illustrates these cost factors for a hypothetical release of 1,500 gallons of 1,1-DCE in the saprolite portion of the groundwater aquifer of the Piedmont region of North Carolina with contamination extending to a depth of 60 feet below ground surface. The first box shows a comparison of the extent of contamination and the work necessary to define that extent for both a 7 μg/L and a 350 μg/L groundwater quality standard. The second box shows the estimated present value cost to assess and clean up to a standard of 7 μg/L with the clean up using pump-and-treat technology and taking 30 years to complete. The third box shows the estimated present value cost to assess and clean up to a standard of 350 μg/L with the clean up involving the injection of chemical oxidants into the contaminated groundwater and taking five years to complete.

(8) ***Provide a description, including the names and addresses, if known, of those most likely to be affected by the proposed rule(s).***

See the sites identified in the table included in item 6 of this Petition.

(9) ***Provide the name(s) and address(es) of the petitioner(s).***

Rhodia Inc.
To the Attention of Mike Shatynski
8 Cedar Brook Drive
Cranbury, NJ 08512

Benne C. Hutson
McGuireWoods LLP
P.O. Box 31247
Charlotte, NC 28231

We appreciate your consideration of this Petition. If you have any questions or need additional information, please call me.

Sincerely,

McGuireWoods LLP

Benne C. Hutson

Benne C. Hutson

Enclosures

cc: Lois Thomas, EMC Clerk
Rhodia – Gastonia Project Management Team
Amanda K. Short

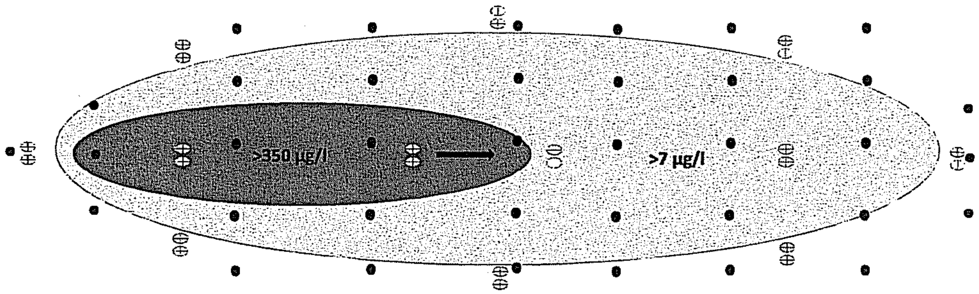
LIST OF EXHIBITS

FIGURE 1

1,1-Dichloroethylene Release Site

Site Characterization	Scenario 1 NCGWQS = 7 µg/l	Scenario 2 NCGWQS = 350 µg/l
Size of plume	3 acres	1 acre
Plume thickness	50 feet	25 feet
DPT gw profiling points	37	24
No. of wells	24	16
No. of gw samples	135	88

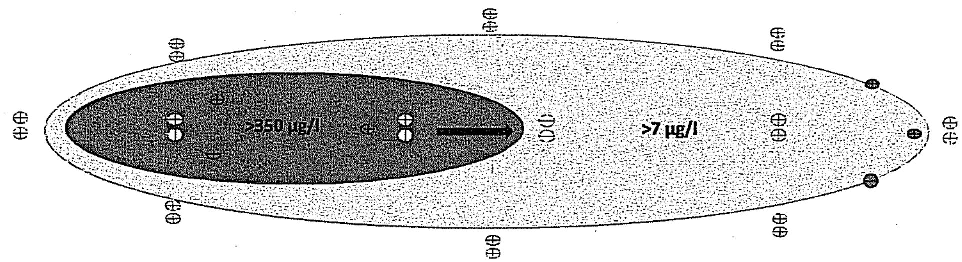
Site Characterization Approach



Scenario 1 - NCGWQS = 7 µg/l

DPT cost	$	25,000
Well installation cost	$	70,000
Analytical cost	$	15,000
Site preparation	$	10,000
Consulting	$	110,000
Site Characterization Cost	**$**	**230,000**
Pump and treat system	$	350,000
O&M (30 years)	$	4,800,000
Total cost	**$**	**5,380,000**

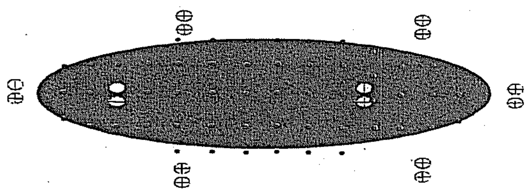
Hydraulic Containment and Source Reduction (Pump and Treat)



Scenario 2 - NCGWQS = 350 µg/l

DPT cost	$	16,000
Well installation cost	$	48,000
Analytical cost	$	8,000
Site preparation	$	5,000
Consulting	$	88,000
Site Characterization Cost	**$**	**165,000**
Treatment volume		40,000 cu. yards
ISCO injections	$	4,000,000
LTM (5 years)	$	250,000
Total cost	**$**	**4,455,000**

In-Situ Chemical Oxidation



Legend

- Shallow/deep monitoring well
- Direct push technology gw profiling point
- Groundwater extraction well
- In-situ chemical oxidation injection points

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7529–1]

RIN 2040–AD67

National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Drinking Water Standards

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Safe Drinking Water Act (SDWA) requires the United States Environmental Protection Agency (EPA) to conduct a periodic review of existing National Primary Drinking Water Regulations (NPDWRs). EPA has completed its review of 69 NPDWRs that were established prior to 1997, including 68 chemical NPDWRs and the Total Coliform Rule (TCR). The intended purpose of the review was to identify those NPDWRs for which current health risk assessments, changes in technology, and/or other factors, provide a health or technological basis to support a regulatory revision that will maintain or improve public health protection.

EPA published its protocol for the review of NPDWRs and its preliminary revise/not revise decisions for the 69 NPDWRs in the April 17, 2002, edition of the Federal Register (67 FR 19030 [USEPA, 2002g]) in order to seek comment from the public. Today's action briefly describes the major comments, other new information, and EPA's current revise/not revise decisions for the 69 NPDWRs.

ADDRESSES: The official public docket for this action is located at EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Contact: Ken Rotert, (202) 564–5280, e-mail: *rotert.kenneth@epa.gov* for inquiries regarding the TCR. For all other technical inquiries contact: Judy Lebowich, (202) 564–4884, e-mail: *lebowich.judy@epa.gov*, or Wynne Miller, (202) 564–4887, e-mail: *miller.wynne@epa.gov*. General information may also be obtained from the EPA Safe Drinking Water Hotline. Callers within the United States may reach the Hotline at (800) 426–4791. The Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION:

Table of Contents

List of Tables

I. General Information

A. Does This Notice Apply to My Public Water System?

This action itself does not impose any requirements on anyone. Instead, it notifies interested parties of the availability of EPA's responses to comments received on EPA's Six-Year Review protocol and the Agency's current revise/not revise decisions for 69 NPDWRs.

B. How Can I Get Copies of Related Information?

1. Docket

EPA has established an official public docket for this action under Docket ID No. OW–2002–0012. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

2. Electronic Access

You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. Once in the system, select "search," then key in the appropriate docket identification number.

Abbreviations and Acronyms Used in This Action

BAT—best available technology
CBI—confidential business information
CCL—contaminant candidate list
CFR—Code of Federal Regulations
CMR—Chemical Monitoring Reform
DACT—diaminochlorotriazine
DEA—desethyl atrazine
DEHA—di(2-ethylhexyl)adipate
DEHP—di(2-ethylhexyl)phthalate
DIA—desisopropyl atrazine
EPA—United States Environmental Protection Agency

EPA/DC—EPA Docket Center
FQPA—Food Quality Protection Act
FR—Federal Register
IOC—inorganic chemical
IRED—interim reregistration eligibility decision
IRIS—Integrated Risk Information System
LCCA—Lead Contamination Control Act of 1988
LCR—Lead and Copper Rule
MCL—maximum contaminant level
MCLG—maximum contaminant level goal
MDL—method detection limit
mg/kg/day—milligram(s) per kilogram of body weight per day
mg/L—milligram(s) per liter
MYP—multi-year plan
NAS—National Academy of Sciences
NCOD—National Contaminant Occurrence Database
NDWAC—National Drinking Water Advisory Council
NPDWR—National Primary Drinking Water Regulation
NRC—National Research Council
NTP—National Toxicology Program
NTNCWS—non-transient non-community water system
Occurrence Methodology Document—Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations
Occurrence Summary Document—Occurrence Summary and Use Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations
OPP—Office of Pesticide Programs
OW—Office of Water
PE—performance evaluation
PHS—Public Health Service
PQL—practical quantitation level
Protocol Document—EPA Protocol for Review of Existing National Primary Drinking Water Regulations
RED—reregistration eligibility decision
RfD—reference dose
ROS—regression on ordered statistics
RSC—relative source contribution
SAB—Science Advisory Board
SAP—Science Advisory Panel
SDWA—Safe Drinking Water Act
SOC—synthetic organic chemical
TCR—Total Coliform Rule
TMDLs—total maximum daily loads
Treatment Feasibility Document—Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations
TT—treatment technique
VOC—volatile organic chemical
WQP—water quality parameter
WS—water supply

II. Background

A. What Is the Statutory Requirement for the Six-Year Review?

Under the Safe Drinking Water Act (SDWA), as amended in 1996, EPA must periodically review existing National Primary Drinking Water Regulations (NPDWRs) and, if appropriate, revise them. Section 1412(b)(9) of SDWA states:

> The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this title. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.

B. What Has the Agency Done To Address the Statutory Requirement?

The Agency developed a systematic process, or protocol, for the review of existing NPDWRs in accordance with the SDWA requirements and applied the protocol to the review of the NPDWRs for total coliforms and 68 inorganic and organic chemicals published prior to the SDWA 1996 Amendments (*i.e.*, pre-1997 NPDWRs). In the April 17, 2002, Federal Register, EPA provided:

- A description of the review protocol;
- A detailed discussion of how the protocol was applied in assessing each of the 69 pre-1997 NPDWRs;
- The preliminary results of each of the technical reviews, and the preliminary decision for each NPDWR; and
- A request for the public to comment on any aspect of the Agency's protocol and preliminary decisions.

Please refer to the April 17, 2002, Federal Register for the detailed discussion of EPA's revise/not revise decisions for each of the 69 NPDWRs. Today's action briefly summarizes the major public comments, other new information, and EPA's current revise/not revise decisions for the 69 NPDWRs. Today's action only discusses in detail those decisions or rationales that were affected by public comments or other new information that has become available since April 2002.

In June 2002, EPA consulted with the Science Advisory Board (SAB) Drinking Water Committee and requested their review and comment on whether the protocol EPA developed based on the National Drinking Water Advisory Council (NDWAC) recommendations was consistently applied and appropriately documented. The SAB provided verbal feedback regarding the transparency and clarity of EPA's decision criteria for making its revise/not revise decisions under the current review. EPA has revised this protocol document to better explain how the decision criteria were applied and will also take the SAB comments into consideration when planning for the next review cycle.

III. EPA's Current Revise/Not Revise Decisions for the 69 Pre-1997 NPDWRs

EPA received comments from 44 commenters on its preliminary revise/not revise decisions in the April 17, 2002, Federal Register. The Agency responded to these comments in the "Public Comment and Response Summary for the Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2003e), which is available in the Water Docket in the EPA Docket Center and at the EPA Dockets Web site *http://www.epa.gov/epadocket/*. Other technical support documents[1] for the decisions discussed in today's action are also available in the Water Docket and at the EPA Dockets Web site *http://www.epa.gov/epadocket/* and the Safewater Web site *http://www.epa.gov/safewater/*.

Based on the Agency's preliminary review, as well as the public comments received and other new information, EPA believes that it is appropriate to revise the Total Coliform Rule (TCR). The Agency also believes that it is not appropriate to revise the 68 chemical NPDWRs at this time. However, for the reasons discussed in sections IV.B.7, IV.B.13, and IV.B.14 of today's action, the Agency has modified the basis of its not revise findings for 1,1-dichloroethylene, lead, and lindane, respectively. Table III–1 reflects the Agency's current revise/not revise decisions for the 69 NPDWRs. As indicated in Table III–1, EPA's decision not to revise an NPDWR at this time is based on one of the following reasons:

- Health risk assessment is in process: As of December 31, 2002, the Agency is currently conducting, or has scheduled, a detailed review of current health effects information. Because the results of the assessment are not yet available, or were not available in time for consideration under the 1996–2002 review cycle, the Agency does not believe it is appropriate to revise the NPDWR at this time. In these cases, EPA will consider the results of the updated

[1] These include: (1) EPA's overall protocol for the review of NPDWRs (USEPA, 2003c); (2) health effects (USEPA, 2003f); (3) analytical methods feasibility (USEPA, 2003a); (4) treatment technology (USEPA, 2003g); (5) consideration of other regulatory revisions (USEPA, 2003b); (6) occurrence and exposure (USEPA, 2003d; USEPA, 2002f); (7) and economic considerations (USEPA, 2002c).

health risk assessment during the 2002–2008 review cycle. If the results of the health risk assessment indicate a compelling reason to reconsider the maximum contaminant level goal (MCLG), EPA may decide to accelerate the review schedule for that contaminant's NPDWR.

• NPDWR remains appropriate after data/information review: The outcome of the review indicates that the current regulatory requirements remain appropriate, and therefore, no regulatory revisions are warranted. Any new information available to the Agency either supports the current regulatory requirements or does not justify a revision.

• New information, but no revision appropriate at this time because:

—Low priority: In EPA's judgment, any resulting revisions to the NPDWR would not provide a meaningful opportunity for health risk reduction or result in meaningful cost-savings to public water systems and their customers. These revisions are a low priority activity for the Agency and, thus, are not appropriate for revision at this time because of one or more of the following considerations: competing workload priorities; the administrative costs associated with rulemaking; and the burden on States and the regulated community to implement any regulatory change that resulted.

—Information gaps: Although results of the review support consideration of a possible revision, the available data are insufficient to support a definitive regulatory decision at this time.

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Table III-1: Current Revise/Not Revise Decisions for the 68 Chemical NPDWRs and the TCR

Not Appropriate for Revision at this Time	Risk assessment in process[1]: chemical currently undergoing an EPA health risk assessment; includes the three initiated as a result of this review (34 NPDWRs)		Acrylamide Alachlor Antimony Asbestos Atrazine Benzo[a]pyrene Cadmium Carbofuran Carbon tetrachloride Copper Cyanide 2,4-D (2,4-Dichlorophenoxyacetic acid) 1,2-Dichlorobenzene 1,4-Dichlorobenzene 1,2-Dichloroethane Di(2-ethylhexyl)adipate Di(2-ethylhexyl)phthalate	Diquat Endothall Ethylbenzene Ethylene dibromide Glyphosate Methoxychlor Pentachlorophenol Polychlorinated biphenyls Simazine Styrene 2,3,7,8-TCDD (Dioxin) Tetrachloroethylene Thallium Toluene 1,1,1-Trichloroethane Trichloroethylene Xylenes
	NPDWR remains appropriate after data/information review (16 NPDWRs)		Barium Dalapon cis-1,2-Dichloroethylene trans-1,2-Dichloroethylene Dinoseb Endrin Epichlorohydrin Hexachlorocyclopentadiene	Mercury Monochlorobenzene Nitrate Nitrite Selenium 2,4,5-TP (Silvex) 1,2,4-Trichlorobenzene Vinyl chloride
	New information, but no revision appropriate because:	Low priority (14 NPDWRs)	Benzene Beryllium Chlordane 1,2-Dibromo-3-chloropropane 1,1-Dichloroethylene 1,2-Dichloropropane Heptachlor	Heptachlor epoxide Hexachlorobenzene Lindane Oxamyl Picloram Toxaphene 1,1,2-Trichloroethane
		Information gaps (4 NPDWRs)	Chromium Dichloromethane	Fluoride Lead
Candidate for Revision	Based on review of "other regulatory revisions" (1 NPDWR)		Total Coliform Rule (TCR)	

[1] As of December 31, 2002, the Agency is currently conducting, or has scheduled, a detailed review of current health effects information.

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IV. Summary of Major Comments and New Information and the Agency's Response

This section summarizes the major public comments, including the Agency's response, and other new information, and explains any modifications to EPA's preliminary revise/not revise decisions. For a more detailed summary of the comments and the Agency's response, please refer to the document: "Public Comment and Response Summary for the Six-Year Review of National Primary Drinking Water Regulation" (USEPA, 2003e).

A. What Did Commenters Say Regarding the Reasonableness and Appropriateness of EPA's Six-Year Review Approach?

1. Overall Approach and Decision Criteria

a. Adequacy of the Review. Commenters generally agreed that EPA had identified the appropriate key elements of the review. However, some commenters stated that the Agency could have done more in some areas (*e.g.*, implementation) and a few commenters expressed the opinion that the Agency's review process contains weaknesses, or was not applied appropriately, because it did not identify any chemical NPDWRs for revision at this time.

EPA Response: The Agency believes that its basic review protocol and decision rationale are reasonable and appropriate. Even though EPA's application of the protocol did not identify any chemical NPDWRs for revision at this time, that is not a reason to reject or modify the protocol. The review did result in the initiation of health risk assessments for three contaminants and efforts to address data gaps/research needs for several other contaminants. Health risk assessments are underway for approximately half of the chemical contaminants addressed in today's action. The Agency expects most of these assessments to be completed within the next few years. When completed, these assessments will support further analysis that may result in different revise/not revise decisions as part of the ongoing Six-Year Review process.

b. Criteria for Deciding that an MCLG/MCL Revision is Appropriate and Definition of "Significant" and "Negligible." While some commenters agreed, others disagreed with the Agency's consideration of estimated changes in occurrence levels and available economic information whenever a health or technological basis to revise a standard. For example, some commenters felt that EPA should revise the MCLG and, as appropriate, the maximum contaminant level (MCL), whenever a health basis exists, regardless of other considerations. A few commenters criticized the Agency for not defining what it considers "significant" and "negligible" gains in public health protection and/or cost-savings in terms of regulatory revision.

EPA Response: Section 1412(b)(9) of SDWA, as amended in 1996, provides the Administrator with broad discretion to determine when a revision to an NPDWR is appropriate. As a part of this determination, the Agency believes it is reasonable to consider whether a potential revision is likely to provide a meaningful opportunity for health risk reduction. This criterion is consistent with the statutory provisions governing the regulatory determination process under section 1412(b)(1)(A) for contaminants not currently regulated. EPA also believes it is reasonable to consider the extent of potential cost-savings for public water systems and their customers when determining whether revisions that potentially would result in a relaxed standard (*i.e.*, where a health basis exists for a less stringent standard) or streamlined implementation are appropriate. These considerations allow the Administrator to better prioritize efforts that are most likely to result in a meaningful opportunity for health risk reduction or cost-savings to public water systems and their customers. Revisions that do not satisfy at least one of these criteria are a low priority activity for the Agency, and thus are not appropriate at this time because of one or more of the following considerations:

- Competing workload priorities;
- The administrative costs associated with rulemaking; and
- The burden on States and the regulated community to implement any regulatory change that resulted.

EPA believes that the determination of whether the impact of a potential revision is "significant" or "negligible" is a matter of judgment that depends on a number of variables, not all of which are amenable to precise definition. However, EPA recognizes that the use of "negligible/significant" terminology may imply more precision and quantitation in the determination than is possible. The Agency also understands that the use of the term "negligible" may imply to some that the Agency is belittling small gains in health risk reduction. This is not the Agency's intent. Accordingly, in today's action, the Agency has explained its rationale more clearly in terms of the criteria noted in the previous paragraph.

c. Authority to Relax an Existing Standard and Deregulation of Low/Non-Occurring Contaminants. Some commenters argued that the Agency should never consider relaxing a standard because doing so, by definition, would lessen the level of public health protection. Other commenters encouraged the Agency to actively consider deregulating contaminants that have low occurrence or do not appear to be occurring in finished water or, at a minimum, to further reduce the frequency of monitoring for these contaminants.

EPA Response: EPA disagrees with those commenters who oppose relaxing a standard for any reason. The legislative history of the SDWA Amendments of 1996 makes clear that Congress envisioned the possibility that a relaxed standard might be appropriate under circumstances that would not result in a lessening of the level of public health protection. In its discussion of potential revisions to an existing drinking water standard, Senate Report Number 104–169 (available electronically at *http://thomas.loc.gov/*) states:

> Amendments made by the bill require that any future standard issued for a contaminant already regulated must maintain or provide for greater protection of the health of persons. Generally, this will preclude the promulgation of a revised standard for a contaminant that is less stringent than the standard already in place. However, there are circumstances under which a standard may be relaxed. The maximum contaminant level goal for a contaminant is set at a level at which there is no adverse effect on the health of persons with an adequate margin of safety. New scientific information may cause the MCLG to be revised and in some cases these revisions may be to less stringent levels. This may lead to a revision of the maximum contaminant level since it need be no more stringent than the MCLG. New information may also allow for a smaller margin of safety because it narrows the range of uncertainty for estimates of health risks. Finally, some substances which have been regulated as carcinogens for ingestion in drinking water may be reclassified (as asbestos has been in the most recent revision) or assigned a threshold for the effect based on new scientific information. In each of these cases, EPA may issue a revised standard for a contaminant that is less stringent than the one it replaces.

(S. Rep.104–169, 104th Cong., 1st Sess. (1995) at 38)

However, because section 1412(b)(9) of SDWA requires that any revision to an existing NPDWR maintain or improve the level of public health protection, EPA believes that a clear, technically-based demonstration regarding the absence of potential risk is necessary to deregulate a contaminant. EPA does not believe it is appropriate to deregulate any currently regulated contaminant at this time because the Agency is not able to make a determination, pursuant to section 1412(b)(9) of SDWA, that there would be no lessening of public health protection if the contaminant were deregulated. The Agency disagrees that evaluation of finished water data is sufficient to consider deregulation of low or non-occurring contaminants. The apparent low or non-occurrence of these contaminants in finished water may be the result of effective treatment processes in place rather than the lack of occurrence in source water.

EPA believes that the existing waiver provisions in the SDWA regulations give States sufficient flexibility to reduce or potentially eliminate monitoring of a chemical contaminant, where appropriate. States that have primacy for the drinking water regulations are responsible for their waiver programs and can grant waivers if a particular pesticide or herbicide has not been previously used, manufactured, stored, transported, or disposed in the area, a system's source water is not susceptible to contamination from the chemical, or the State has determined the system is not vulnerable. The State can grant waivers for individual contaminants, a group of contaminants, or issue an area-wide waiver (*see* 40 CFR 141.23 (b) and (c), and 141.24 (f) and (h)). In addition, States can adopt alternative monitoring strategies as long as the approach is as stringent as the Federal requirements (USEPA, 1997b).

2. Health Effects Technical Review

a. Contaminants Undergoing Health Risk Assessments. A few commenters raised issues with respect to the 36 chemical contaminants for which health risk assessments were underway when EPA published its preliminary revise/not revise decisions in the April 17, 2002, **Federal Register**. In particular, these commenters wanted to know the process that EPA plans to follow to review each NPDWR once the risk assessment is completed, including when that review would occur and when an accelerated review would be appropriate.

EPA Response: Between April and August 2002, the Agency completed health risk assessments for 2 of the 36 contaminants: 1,1-dichloroethylene and lindane. The results of those assessments and the impact on the Agency's revise/not revise decisions are discussed in sections IV.B.7 and IV.B.14, respectively, of today's action. NPDWRs for the remaining contaminants for which health risk assessments are in process will be reviewed as a part of the 2002–2008 review cycle. However, if in the Agency's judgment, a compelling reason exists to revisit the "not revise" decision sooner, EPA may accelerate the review cycle for that NPDWR. In reviewing these regulations, EPA expects to apply an approach consistent with the protocol used for the current review. That is, the Agency will consider the same key elements and apply the same basic decision tree for making a revise/not revise decision. The key elements of the review include health effects technical review, technology review, other regulatory revisions review, and, if appropriate, occurrence/exposure analyses and consideration of available economic information (see 67 FR 19030 at 19038, April 17, 2002 (USEPA, 2002g)).

b. Other Issues Related to the Health Effects Technical Review. One commenter stated that the Agency risk assessments underestimate risk because absorption of chemicals through the skin, lung, and nose is not "adequately" taken into account. Another commenter encouraged the Agency to evaluate the literature for potential reproductive and developmental effects for chemicals with zero MCLGs since risk management strategies, such as monitoring frequency or treatment requirements, may be affected by such information.

EPA Response: EPA disagrees that the Agency underestimates risk when deriving MCLGs. The Agency takes multiple routes of exposure into account by including a relative source contribution (RSC) in its calculation of an MCLG value. The RSC compares exposure from air, food, and drinking water and uses the data in allocating a portion of the total exposure to drinking water. When exposure data for the chemical are not available, EPA assumes that the RSC from drinking water is 20 percent of the total exposure. This allows 80 percent of the total exposure to come from sources other than drinking water, such as exposure from food, inhalation, or dermal contact.

EPA recognizes the possibility that some chemicals with zero MCLGs may also be of reproductive and/or developmental concern. EPA is investigating these endpoints and their potential impact on monitoring frequency or treatment requirements. However, the Agency does not believe the analysis can be completed during the current review cycle without significantly delaying the current revise/not revise decisions. To the extent possible, EPA will consider the results of this analysis and any additional information during subsequent Six-Year Reviews.

3. Analytical Methods Feasibility Technical Review

Commenters generally supported the Agency's approach of using Performance Evaluation (PE) Water Supply (WS) data and the 10 times method detection limit (MDL) multiplier to evaluate possible changes in analytical feasibility for several of the contaminants under this Six-Year Review. A few commenters agreed that the WS data are a valuable source of information for evaluating interlaboratory performance and for developing practical quantitation levels (PQLs). However, the same commenters questioned whether the approach of using PE WS data will be possible for future reviews since the Agency's laboratory certification program that once collected this information has been externalized to private providers. These commenters questioned whether the externalized or privatized data would be sufficient for the determination and/or re-evaluation of PQLs. In addition, at least one commenter suggested that it may be appropriate (in the next Six-Year Review) to re-evaluate the policy of basing the PQL on only EPA Regional and State laboratory results, and recommended that the Agency include commercial and large utility laboratory results. According to the commenter, these laboratories (commercial and large utility) have demonstrated "significant innovation in method development and improved quantitation."

EPA Response: EPA agrees that the WS studies have been a valuable source of information for determining PQLs. At this time, the Agency has not determined whether the privatized data will be sufficient for the purposes mentioned by the commenter. In addition, the Agency has not yet determined how best to gather data to determine and/or reassess PQLs for future reviews. The Agency is in the process of evaluating acceptable options. The policy for determining the most appropriate methodology for calculating PQLs for drinking water contaminants is outside the scope of the Six-Year Review.

4. Review of Treatment Technologies and Related Issues

Commenters suggested that, while EPA's review of existing NPDWRs was generally consistent with the NDWAC recommendations to EPA (NDWAC, 2000), the Agency's review of treatment technologies which support the regulations should be expanded. Specifically, commenters recommended that EPA review all treatment technique (TT) requirements and allow for changing or expanding these TT requirements where new information warrants such a change.

EPA Response: EPA continues to believe its approach to reviewing TT requirements is appropriate. The "EPA Protocol for the Review of Existing NPDWRs" (Protocol Document) discusses when it is appropriate for the Agency to consider revisions to TT-type regulations (see sections II.C and III.B of the Protocol documents) (USEPA, 2002d; USEPA, 2003c). The Agency discussed the review of the four chemical treatment technique NPDWRs (*i.e.*, acrylamide, copper, epichlorohydrin, and lead) in both the draft and final "Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations" (Treatment Feasibility Documents) (USEPA, 2002b; USEPA, 2003g). The Agency has no specific information that provides a basis for revisions to TT requirements at this time. However, EPA believes that research data in a number of treatment-related areas may be useful in future reviews of NPDWRs. The Agency is ommitted to working with stakeholders to identify and prioritize treatment-related research needs, and to work with EPA's research partners to address the highest priority needs.

5. Review of Implementation-Related Issues

While several commenters felt overall that EPA's Six-Year Review protocol was reasonable and appropriate, they encouraged EPA to consider implementation-related modifications (*i.e.*, "other regulatory revisions") as a reason to revise a rule, even if there were no basis to revise the MCLG and/or MCL/TT requirements.

EPA Response: Implementation-related issues are the primary reason for the Agency's decision to revise the TCR at this time (67 FR 19030 at 19085, April 17, 2002 (USEPA, 2002g)), so it is clear that EPA considered implemented-related issues in its review. The Protocol Document (USEPA, 2002d; USEPA, 2003c) identifies the conditions under which the Agency will consider implementation-related revisions. EPA continues to believe these criteria are appropriate. During the current review, none of the identified potential ıplementation-related revisions ·taining to the chemical NPDWRs, in EPA's judgment, met the stated criteria for reasons documented in EPA's final document, "Consideration of Other Regulatory Revisions for Chemical Contaminants in Support of the Six-Year Review of National Primary Drinking Water Regulations" (USEPA, 2003b).

6. Review of Occurrence and Exposure

a. Occurrence Database Concerns. A few commenters asked for information regarding next steps for the National Contaminant Occurrence Database (NCOD). Another commenter pointed out that States have been willing to assist EPA by providing occurrence data beyond what is required of them. However, the commenter raised concerns that he/she felt EPA needs to address to facilitate further data sharing.

Some commenters expressed concern about the completeness and representativeness of the 16-State data set used for the Six-Year Review. One commenter suggested that the Agency should have issued an Information Collection Request to obtain more complete data for the Six-Year Review analysis.

EPA Response: The Agency is updating the NCOD to provide sample data that have been quality checked and used in various EPA analyses. This update to NCOD includes unregulated occurrence data collected prior to 1999 as well as the latest Unregulated Contaminant Monitoring Rule data (64 FR 50556, September 17, 1999 (USEPA, 1999b)) reported by laboratories for public water systems required to report results. It also includes the data used for the Six-Year Review of regulated contaminants. EPA appreciates that some States are willing to share their full compliance monitoring records with the Agency, even though it is not required. The Agency and the States are continuing to work together to establish a protocol for data sharing, including safeguards to prevent misuse and misinterpretation of data.

The 16-State cross-section data set compiled for occurrence analyses for the Six-Year Review is the largest compliance monitoring data set for drinking water assembled by EPA to date. The design and construction of the 16-State cross-section data set was based on the fact that contaminant occurrence varies spatially (geographically) due to differing patterns of population, land use, chemical use, geology, hydrology, and climate. The detailed description of the "pollution-potential" and geographic diversity considerations, and the derived balanced cross-section of States (that was developed to be collectively indicative of national occurrence) is included in the "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations" (Occurrence Methodology Document) (USEPA, 2003d). EPA selected its 16-State cross-section to be as representative as possible of national contaminant occurrence. In EPA's judgment, these States provide a reasonable cross-section of agricultural and industrial pollution potential, as described in the Occurrence Methodology Document, and also provide geographic coverage of the United States. Therefore, EPA believes that the data assembled from these States is the most representative data currently available of national contaminant occurrence.

The Agency did receive occurrence data from States other than those in its 16-State cross-section. However, many State data sets contained incomplete records (*e.g.*, no water type or population records specified) or had other quality problems. Therefore, they were not included in the analyzed data set.

b. Occurrence Analysis Methodology. One commenter noted that while the occurrence estimation methodology has several strengths, it also has a number of flaws. The commenter was concerned about the large proportion of non-detected observations in the occurrence data, and the difficulty of verifying the assumptions made by the Agency. The commenter agreed that EPA's occurrence analysis may represent a "decent" estimate given the limitations of the data. The commenter also noted that the occurrence estimation methodology is premised on "subjective decisions or qualitative observations * * * rather than documented, statistically-based quantitative ones" and would like to have seen alternate approaches used to provide confirmation of the estimates. In addition, the commenter questioned why the Agency used "modeled data sets to test the model rather than a standard statistical strategy of basing the model on a portion of the data set and using the remainder to test the model."

One commenter stated that the Stage 2 analysis (Bayesian analysis) was poorly described and that this conflicts with the transparency requirements of the 1996 SDWA Amendments. In addition, the commenter asked EPA to clarify how the occurrence data from other survey efforts, which are summarized in "Occurrence Summary and Use Support Document for the Six-Year Review of Existing National Primary Drinking Water Regulations"

(Occurrence Summary Document) (USEPA, 2002f), were used to inform the modeling effort.

EPA Response: EPA's occurrence model development work was significantly revised to reflect peer review comments prior to the March 2002 Occurrence Methodology Document (USEPA, 2002e) and the April 17, 2002, **Federal Register**. The additional work involved the development of a detailed simulation study to evaluate the Bayesian model. EPA evaluated the performance of the Bayesian estimator and an alternative occurrence estimation approach, the Regression on Ordered Statistics (ROS) method, against synthetic data (*i.e.*, data developed with known national contaminant occurrence distributions). This simulation study also enabled an explicit evaluation of the validity of the assumption of a log-normal distribution of the data.

The simulation study was conducted using varying conditions of a correctly and incorrectly specified model, and synthetic data sets developed with high and low amounts of non-detected data. The study findings indicated that the Bayesian estimator performed well at estimating the distributions of contaminant concentration means (especially in the upper tails), performed better than the alternate approach (*i.e.*, the ROS method), and ccurately estimated the uncertainty of the distributional estimates. The Agency believes that this analysis supports the validity of EPA's analytical approach. The Bayesian model was tested against the ROS approach because the ROS method is an accepted drinking water contaminant occurrence estimation approach and was used to estimate occurrence for the recent arsenic rule. These findings were all included and described in the Six-Year Review's Occurrence Methodology Document.

EPA has attempted to make its occurrence analysis as clear as possible. In response to the concerns raised by the peer reviewers, a less technical description of the occurrence estimation methodology, aimed at the general reader, was added to the main body of the document. A detailed description of the analysis, intended for readers with technical expertise, including the complete computer code used for model analysis, was incorporated into an appendix of the document. EPA agrees that its estimation methodology is complex, but also believes that it is as transparent as possible while still providing a technically accurate description of the Agency's analysis. The use of simple national occurrence (statistical) assessments is not possible at this time because there is no national database with a complete collection of regulated contaminant occurrence data. Thus, there is no ideal basis for comparison of national occurrence studies (*i.e.*, the true system contaminant means and national distributions of contaminant occurrence are not, and cannot, be known). The validation approach suggested by the commenter (*i.e.*, basing the model on a portion of the data set and using the remainder to test the model) is intended for a regression-type of model using observed system means to develop a model for system-specific predictions. This approach is not possible for the six-year occurrence assessments, since, to the best of EPA's knowledge, data on the true individual system contaminant mean concentrations and national distributions are not available.

Regarding the other survey studies included in the Occurrence Summary Document, few, if any, provide the quantitative analytical results and national, representative coverage that would enable direct comparison to, or inclusion in, the Six-Year Review estimation analyses conducted with the 16-State cross-section occurrence data.

c. Other Issues Related to the Occurrence Technical Review. One commenter stated that the Agency's current approach to estimate occurrence, employing a conservative methodology and making conservative simplifying assumptions in the absence of definitive data, was appropriate. On the other hand, the commenter argued that it was not appropriate for the Agency to conduct as massive a data collection and analysis project as was undertaken without clear quantitative objectives for the analysis identified a priori. The commenter noted that it was not apparent from either the April 17, 2002, **Federal Register** or the Occurrence Methodology Document (USEPA, 2002e) that the Agency undertook an effort to set performance objectives for the occurrence estimation.

The commenter felt that the Occurrence Methodology Document does not allow the reader to determine if the data are well apportioned among the categories for which results are reported. They also noted that they were unable to find indications in the support document that such an analysis was undertaken in preparation for constructing the Bayesian model. The commenter stated that the support document does not include actual numeric counts or ranges of detected values and suggested that it would be useful to have this information by contaminant, State, system size category, and water type, as well as an explicit count of non-detects by this same matrix.

EPA Response: There are several general approaches when undertaking and designing studies that require large amounts of data. As the commenter states, a priori data quality objectives are part of one research approach where study objectives (including technical statistical performance measures) are set, determinations are made on how to meet those objectives, and then the study is designed and implemented accordingly. This ideal was not practical for the national occurrence study conducted for the Six-Year Review because EPA did not have the resources to generate original data, and was thus dependent on the data that could be obtained from the States. The approach taken by the Six-Year Review was to gather a large amount of data that, in aggregate, was expected to be indicative of national contaminant occurrence, develop an occurrence estimation model that built upon what has been learned from recent regulatory development work, and then evaluate how good the resulting model estimates are.

As discussed in section IV.A.6.b of today's action, the true national distributions of contaminant occurrence cannot be known. The 16-State national cross-section data set used for the Six-Year Review is the largest compliance monitoring database for drinking water compiled by EPA to date. The database represents approximately 37 percent of the total number of public water systems and 43 percent of the total population served by public water systems in the United States. External peer reviews assessed the approach for developing the national cross-section and its "representativeness" separately under the Chemical Monitoring Reform (CMR) project (in 1998/1999) (USEPA, 1999c) and the Six-Year Review project (USEPA, 2002e), and provided generally favorable comments.

The data management and cross-section development have been described in detail in the support documents for the CMR and the Six-Year Review. Further tabulations of the data have been generated and presented, as the commenter requested, in the final Occurrence Methodology Document (USEPA, 2003d). This information includes the numbers and percentages of analytical detections and non-detections for each contaminant in each of the system size and source water type categories. Generally, because of the large amount of data and the manner in which the Bayesian model handles data, the distribution of observations across the various categories does not significantly affect EPA's estimates. The number of analytical records differed by contaminant. EPA evaluated 27,648 to 93,062 analytical records for the individual inorganic chemicals, 32,606 to 121,327 records for the synthetic organic chemicals, and 123,229 to 201,235 records for the volatile organic chemicals. Most importantly, the Stage 2 occurrence model also quantifies the uncertainty of the estimates in the different categories of system size and source water type. Hence, the statistical significance of differences in occurrence between the categories can be easily assessed. However, the Agency believes it is more appropriate to consider the universe of potentially affected systems within the 16-State cross-section, rather than individual system categories, when making its revise/not revise decisions as part of the Six-Year Review process.

7. Consideration of Available Economic Information

Some commenters stated that, while the Agency's review of NPDWRs was generally consistent with NDWAC recommendations to EPA (NDWAC, 2000), it is not clear how the Agency took economic factors into account.

EPA Response: An EPA memorandum, dated March 18, 2002, describes the Agency's qualitative evaluation of economic factors (USEPA, 2002c). This memorandum was cited in the April 17, 2002, **Federal Register** and available in the docket for the Six-Year Review (Docket No. OW–2002–0012). It notes that detailed economic analyses were not deemed by the Agency to be necessary to support its decisions of whether or not to revise a particular NPDWR. Rather, a qualitative assessment, based on the extent of occurrence of a contaminant at the MCL, as well as at alternative levels, was undertaken to inform the Agency's judgment about whether possible changes to an MCL offered a meaningful opportunity for health risk reduction and/or cost-savings to public water systems and their customers. EPA has conducted this assessment for 15 of the chemical NPDWRs for which the Agency had determined that a potential health or technological basis may exist for considering a revision to the MCLG/MCL.[2] EPA compared the estimated occurrence and exposure values at the current MCL and at potentially revised regulatory level(s). For 14 of these chemical NPDWRs, the Agency's assessment showed that the differences were small. In EPA's judgment, these differences are unlikely to provide a meaningful opportunity for health risk reduction or cost-savings to public water systems and their customers. After consideration of these factors, EPA decided that any revision would be a low priority activity for the Agency, and, thus, not appropriate to revise at this time because of: Competing workload priorities; the administrative costs associated with rule making; and the burden on States and the regulated community to implement any regulatory change that resulted. In the case of dichloromethane, the Agency did not have sufficient data to recalculate the PQL to support any potential regulatory revision and thus placed it in the data gaps category.[3]

B. What Comments or New Information Did EPA Receive on Chemical Contaminant-Specific Issues?

1. Alachlor

One commenter stated that the Office of Pesticide Programs (OPP) found that the chloroacetanilide pesticides (acetochlor, alachlor, and butachlor) should be considered as a group of chemicals having a common mechanism of toxicity due to their ability to cause nasal turbinate tumors. The commenter believes EPA therefore should adopt a strong total chloroacetanilide pesticide standard that would strengthen the current standards.

EPA Response: Butachlor and acetochlor do not presently have an NPDWR and thus, are not included in the Six-Year Review. However, acetochlor is included on the Contaminant Candidate List (CCL) and may in the future be considered as a candidate for regulation. Alachlor is a regulated drinking water contaminant and is included in the Six-Year Review. It is currently undergoing a risk assessment and, therefore, the Agency believes that revision of the NPDWR is not appropriate at this time.

If the Agency decides to regulate either acetochlor or butachlor in the future, EPA may consider regulating them as a group, including alachlor, following a cumulative risk assessment process for pesticides that have a common mechanism of toxicity. It would be premature to propose a total chloroacetanilide pesticide standard until a cumulative risk assessment is completed because this analysis could impact the Agency's evaluation of specific members of this group, or the group as a whole.

2. Antimony

a. Health Effects. A number of commenters have suggested that the current MCLG and MCL of 0.006 milligrams per liter (mg/L) for antimony need to be revised. Some of the reasons given were:

- The study used to derive the current MCLG (Schroeder *et al.*,1970) is not consistent with current good laboratory practice guidelines and there are several newer studies of antimony toxicity that should be considered in deriving a new reference dose (RfD).
- Animals used in the Schroeder *et al.*, 1970 study had a viral infection. To compensate for this infection, adjustments were made to the size of the animal groups in an attempt to salvage the data.
- The antimony compound used in the Schroeder *et al.*, 1970 study was potassium antimony tartrate, the most water soluble and toxic form of antimony. Antimony found in drinking water is likely to be in the form of less toxic trivalent and pentavalent antimony species. Therefore, basing the MCLG on the most toxic species of antimony (potassium antimony tartrate) is likely to overestimate the risk posed by antimony in drinking water.

EPA Response: EPA agrees that the MCLG and MCL for antimony may need to be re-evaluated. EPA is in the process of developing a new health risk assessment for antimony, taking into consideration new studies that have become available on the toxicity of antimony. EPA expects to complete the health risk assessment for antimony in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003h)). As a result of the ongoing health risk assessment, a revision to the antimony standard is not appropriate at this time, and antimony will be re-evaluated as part of the next Six-Year Review process.

b. Treatment and Implementation Issues. Several commenters questioned the appropriateness of the antimony MCL, and the effectiveness of using the EPA-designated best available technologies (BATs) to meet the antimony MCL. A few small systems in Utah have levels of antimony in water at or above the MCL value of 0.006 mg/L. These systems were granted

[2] These 15 chemical NPDWRs are: Benzene; beryllium; chlordane; 1,2-dibromo-3-chloroproppane dichloromethane; 1,1-dichloroethylene; 1,2-dichloropropane; heptachlor; heptachlor, epoxide; hexachlorobenzene; lindane; ...yl; picloram; toxaphene; and 1,1,2-...oroethane.

[3] The other three NPDWRs in the data gaps category, chromium, fluoride, and lead, were placed there for reasons other than occurrence and economic considerations. Chrominum is in the data gaps category because of the studies being conducted by the National Toxicology Program studies. Fluoride is in the data gaps category pending a National Academy of Sciences update of the health risk assessment and review of the RSC assumptions. Lead is in the data gaps category based on consideration of public comments (see section IV.B.13 of today's action).

exemptions contingent upon testing and installation of treatment by March 2004.

These systems are investigating treatment options for the removal of antimony from their source water. Commenters submitted supporting data documenting the results of their testing and cost analyses. According to commenters, on-site testing indicated that the designated BATs (*i.e.*, reverse osmosis and coagulation/filtration) and most of the other tested treatments were ineffective and/or prohibitively expensive due to: raw water quality concerns; water conservation needs; current costs for water production; and other concerns, such as waste water management. However, commenters did identify treatment options that may be feasible, but these may require further investigation prior to full scale use.

EPA Response: As discussed in the April 17, 2002, **Federal Register** and as noted in the previous response in section IV.B.2.a, EPA does not believe it is appropriate to consider revisions to the NPDWR for antimony at this time because of the ongoing health risk assessment (67 FR 19030 at 19051 (USEPA, 2002g)).

When EPA initially promulgated the antimony NPDWR in 1992, the Agency estimated that 200 public water systems would be affected (USEPA, 1992). EPA recognizes that implementation of this standard may present challenges for a localities. Although the use of the designated BATs for antimony may not be appropriate in some cases, as long as systems comply with the MCL, they are not limited to these technologies.

EPA believes that the treatment data generated by the commenters may be valuable and may provide insight into potential alternative treatment technologies. The Agency has revised the document, "Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In support of EPA Six-Year Review of National Primary Drinking Water Regulations" (Treatment Feasibility Document) (USEPA, 2003g) to refer to these preliminary test data as they may be applicable to the development of potential new treatment technologies for the removal of antimony and other contaminants.

3. Atrazine

a. Health Effects. Several commenters addressed the EPA decision not to consider revision of the MCL for atrazine at this time. Some of these commenters stated that EPA should use the risk assessment, released by OPP in May 2002, as a basis for reconsidering the atrazine NPDWR. One of the commenters noted that the 2002 risk assessment is based on reproductive and developmental endpoints which represents a change from the toxicity endpoint that formed the basis of the current MCLG. Two commenters stated that the MCL for atrazine should be revised upward because of the results of the 2002 OPP risk assessment in which the RfD increased and the cancer classification changed from "possible human carcinogen" to "not likely to be a human carcinogen." The commenters stated that the change in the cancer assessment implies elimination of the additional 10-fold risk management factor used in 1991 to derive the MCLG/MCL for atrazine. Another commenter stated that atrazine should be regulated using a non-linear approach which recognizes that there is a level at which no known health effects occur and that these findings must be part of the new MCL.

Conversely, another commenter stated that there is substantial new evidence from epidemiological and occupational studies that atrazine poses a serious cancer risk, and that it is an endocrine disruptor at low levels. The commenter believes EPA should adopt a revised atrazine and total triazine standard lower than (*i.e.*, more stringent than) the current 0.003 mg/L standard for atrazine.

A commenter also urged the Agency to:

- Provide a definitive timetable for review of the standard;
- Outline a preliminary scope for its review of the standard; and
- State the underlying premise for the scope of the review.

Other commenters stated that the existing NPDWR only regulates the parent compound atrazine, and that a revised NPDWR should include the chloro-metabolite degradants (*i.e.*, diaminochlorotriazine (DACT), desethyl atrazine (DEA), and desisopropyl atrazine (DIA)). These commenters believe that inclusion of the chloro-metabolites would strengthen compliance monitoring programs for public water systems under SDWA and thereby strengthen public health protection. They stated that a regulation for atrazine and the chloro-metabolites should be developed and promulgated within the next 12 to 18 months. Another commenter stated that since the Agency has found that atrazine, simazine, propazine, and the degradants DACT, DEA, and DIA have a common mechanism of toxicity, these should be regulated in a total triazine regulation.

EPA Response: EPA does not believe it is appropriate to consider revisions to the NPDWR for atrazine at this time because the revised risk assessment has not been finalized. For purposes of the Six-Year Review protocol, EPA considers a risk assessment final when an Interim Reregistration Eligibility Decision (IRED), Reregistration Eligibility Decision (RED), and/or IRIS assessments are complete.[4] Even though an IRED for atrazine was signed on January 31, 2003, an amended IRED is scheduled to be released in October 2003 which will include a Scientific Advisory Panel (SAP) peer review of new data related to health effects. Based upon the outcome of the SAP review, the October 2003 IRED may include additional information that could impact a revise/not revise decision. Therefore, EPA does not believe it is appropriate to consider possible revisions to the NPDWR at this time.

In reviewing the atrazine regulation, EPA will apply an approach consistent with the protocol used for the current review. The Agency will consider the same key elements (*i.e.*, health effects review, technology review, other regulatory revisions review, and, if appropriate, occurrence/exposure analyses and consideration of available economic information) and apply the same basic decision tree for making a revise/not revise decision.

To address the issue of regulating the triazines as a group, the Agency is evaluating the unregulated triazines as part of the CCL process. When the risk assessment is completed for atrazine, the Agency will consider whether or not there are compelling reasons for considering a revision to the atrazine regulation or to wait until the risk assessment for the triazines, which considers issues of cumulative risk, is finalized. EPA will use the CCL regulatory determination process in deciding whether the triazines should be regulated as a group.

b. Costs of Treatment. Commenters stated that the costs associated with not revising the MCL are great. These commenters are concerned that State agencies will be required to develop total maximum daily loads (TMDLs) based on 303(d)[5] listings resulting from

[4] The IRED is an intermediate decision for an individual pesticide that does not take into account cumulative risk issues for pesticides with a common mode of action. The RED does include cumulative risk. If an IRIS assessment is also in process when the IRED or RED is signed, EPA will make a case-by-case decision on whether to wait for the IRIS assessment before considering possible revisions to the NPDWR.

[5] Section 303(d) of the Clean Water Act and the implementing regulations (40 CFR 130.7) require States to develop TMDLs for waters where required point and nonpoint source pollution controls are not stringent enough to attain or maintain compliance with State water quality standards after the application of technology-based and other

Continued

an outdated MCL which creates a burden on State and local government, its citizens, and diverts limited resources away from programs that provide real benefits. Some commenters also stated that the treatment costs to hundreds of community water systems are considerable. One commenter also stated that these are real dollars that would otherwise be available for emergency services, education, nutrition programs, and other vital programs that are the responsibilities of local and State agencies.

EPA Response: As stated in the previous response in section IV.B.3.a, EPA does not believe it is appropriate to revise the NPDWR for atrazine at this time because the risk assessment is not yet final. If EPA decides to revise the NPDWR for atrazine, economic factors, including feasibility and an assessment of costs and benefits, will be taken into consideration for the drinking water program.

4. Beryllium

Two commenters believed that the current drinking water standard for beryllium is more stringent than necessary for the protection of public health and felt that EPA should adopt a higher value for the beryllium standard. These commenters disagreed with EPA on the use of an uncertainty factor of 300 in deriving the 1998 RfD. The commenters stated the use of uncertainty factors of 3 for database uncertainty, 10 for extrapolating data from a dog study to humans, and 10 for intraspecies variation is inappropriate. The commenters stated that EPA has the authority to raise the current drinking water standards for beryllium based on new information that allows for a smaller margin of safety than the one used by EPA. The commenter felt that the current standard for beryllium is "lower than necessary to protect the public from beryllium toxicity and results in clean-up standards that are lower than naturally occurring level of beryllium in water sources and soils." This commenter also expressed concern that the local application of the Federal drinking water standard to private wells in some cases caused undue concerns among users of those wells.

EPA Response: One of the purposes of the Six-Year Review is to determine if the MCL of a chemical should be changed based on a revised RfD or cancer classification. Analytical methods and treatment technologies are considered, as well as occurrence in public water systems. The RfD for beryllium was revised in 1998 based on extensive Agency internal and external reviews, and is unlikely to be revised in the absence of new data. The 1998 assessment also provided separate cancer classification for inhalation and oral exposures (USEPA, 1998). In the revised assessment, the carcinogenicity of beryllium by the inhalation route was described as "likely," while that by the oral route of exposure "cannot be determined." As discussed in the April 17, 2002, **Federal Register**, the Agency considered the occurrence of beryllium at both potentially higher and lower regulatory levels. EPA concluded that a revision to the NPDWR would not result in a meaningful opportunity for health risk reduction or cost-savings to public water systems and their customers. As a result, revision of this NPDWR is a low priority action for the Agency and is not appropriate at this time.

The goal of drinking water standards is to protect public health. Therefore, it does not matter whether the source of contamination is naturally-occurring or man-made. While EPA appreciates the information on private wells, the SDWA requirements do not apply to private wells (*i.e.*, wells that are not part of a "public water system"). The costs and benefits of a drinking water standard are assessed only with regard to the impacts on public water systems and their customers.

5. Carbofuran

Some commenters mentioned that the Agency concluded that N-methyl carbamates, including carbofuran, should be considered as a class because they have a common mechanism of toxicity. Therefore, they believe EPA should issue a stronger standard for total N-methyl carbamates, including carbofuran, which would be more stringent than the current carbofuran standard of 0.04 mg/L.

EPA Response: EPA is re-evaluating the toxicity of carbofuran. However, a final assessment has not been issued by EPA. The Agency considers N-methyl carbamate pesticides as a group of chemicals having a common mechanism of toxicity due to their ability to inhibit acetylcholinesterase. However, it is not appropriate to revise the NPDWR for carbofuran at this time because the Agency has not yet completed the final health risk assessment for carbofuran or the other N-methyl carbamates.

6. Chromium

One commenter requested that EPA move quickly in making a revise/not revise determination once the new data on chromium become available from the National Toxicology Program (NTP) studies of the health effects of chromium VI.

EPA Response: The NTP studies that the commenter refers to should be available before the end of the next Six-Year Review cycle. Meanwhile, EPA is continuing to follow the progress of NTP in conducting subchronic and chronic studies of chromium VI.[6] NTP made the data from the subchronic portion of the study available to the public in June 2002 (NTP, 2002). A peer review meeting was held at NTP on July 24, 2002. EPA will examine the peer review report covering the subchronic data once it becomes available. Once the subchronic and chronic studies are completed, the health effects data will be evaluated with regard to their impact on the present RfD and cancer assessment, and integrated with the occurrence and analytical method data before making a new revise/not revise decision.

7. 1,1-Dichloroethylene

In the April 17, 2002, **Federal Register**, the Agency preliminarily placed 1,1-dichloroethylene in the no revision category because a health risk assessment was pending at the time of publication. Since the publication of the April 17, 2002, **Federal Register**, the Agency has finalized the risk assessment for 1,1-dichloroethylene. The remaining paragraphs in this section include a brief background discussion about the original promulgation of the 1,1-dichloroethylene NPDWR, the results of the appropriate six-year technical reviews and the Agency's revise/not revise decision.

a. Background. EPA published the current NPDWR for 1,1-dichloroethylene on July 8, 1987 (52 FR 25690 (USEPA, 1987)). The NPDWR established an MCLG and an MCL of 0.007 mg/L. The Agency based the MCLG on an RfD of 0.009 milligram per kilogram of body weight per day (mg/kg/day) and a cancer classification of C, possible human carcinogen.

b. Technical Reviews. EPA updated the risk assessment for 1,1-dichloroethylene on August 13, 2002 (USEPA, 2002i). The new risk assessment established an RfD of 0.046 mg/kg/day, based on the same toxicological study as that of the MCLG, but using an uncertainty factor of 100

required controls. A TMDL establishes the maximum amount of a pollutant that may be introduced into a waterbody while still ensuring attainment and maintenance of water quality standards.

[6] Since NTP is posting its progress on its internet site *http://ntp-server.niehs.nih.gov/htdocs/Studies/HexChromium/hexchromiumpg.html*, EPA and the public will be able to evaluate the new data relative to the existing EPA assessment for chromium VI as it is released.

instead of 1,000, and using benchmark dose modeling for the dose-response analysis. Under the 1986 cancer guidelines (51 FR 33992, September 24, 1986 (USEPA, 1986)), 1,1-dichloroethylene was assigned to Group C, possible human carcinogen. Under the draft revised "Guidelines for Carcinogen Risk Assessment" (USEPA, 1999a), the data for 1,1-dichloroethylene were considered inadequate for an assessment of human carcinogenic potential by the oral route.

Based on the change in RfD for 1,1-dichloroethylene, using a 20 percent RSC and a 10-fold risk management factor for possible carcinogenicity, EPA used 0.03 mg/L as a level for evaluating the occurrence data. Without the use of the 10-fold risk management factor, EPA also used 0.3 mg/L as a level for evaluating the occurrence data.

Analytical or treatment feasibility do not pose any limitations for the current MCL and would not be a limiting factor at the 0.03 mg/L or the 0.3 mg/L level (USEPA, 2002a; USEPA, 2003g). The Agency's review of possible "other regulatory revisions" did not identify any issues that are specific to 1,1-dichloroethylene (USEPA, 2003b).

EPA evaluated the results of the occurrence and exposure analyses for 1,1-dichloroethylene to determine whether possible changes to the standard would be likely to result in a meaningful opportunity for cost-savings to public water systems and their customers (USEPA, 2003d). Table IV–1 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for the current MCL (0.007 mg/L), and for two higher levels (0.03 mg/L and 0.3 mg/L). Based on the detailed analysis, it appears that 1,1-dichloroethylene is unlikely to occur at concentrations above 0.007 mg/L in the States used for the cross-section.

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Table IV-1: 1,1-Dichloroethylene Occurrence[1]

Level (in mg/L)		16-State Cross-Section - Total Systems with Data	Estimated # of Systems > Level Evaluated (credible intervals)[3,6]		Estimated % of Systems > Level Evaluated (credible intervals)[3]	
Systems[2]						
Upper Level Evaluated (without 10-fold risk management factor)[4]	0.3	19,101	0	(0-0)	0.000%	(0.000% - 0.000%)
Lower Level Evaluated (with 10-fold risk management factor)[5]	0.03	19,101	0	(0-0)	0.000%	(0.000% - 0.000%)
Current MCL	0.007	19,101	3	(1-6)	0.0144%	(0.00518% - 0.0311%)
Population Served by Systems[2]						
Level (in mg/L)		**16-State Cross-Section - Total Population Served by Systems with Data**	**Estimated Population Served by Systems > Level Evaluated (credible intervals)[3]**		**Estimated % of Population Served by Systems > Level Evaluated (credible intervals)[3]**	
Upper Level Evaluated (without 10-fold risk management factor)[4]	0.3	106,607,600	0	(0-0)	0.000%	(0.000% - 0.000%)
Lower Level Evaluated (with 10-fold risk management factor)[5]	0.03	106,607,600	0	(0-0)	0.000%	(0.000% - 0.000%)
Current MCL	0.007	106,607,600	14,400	(0 - 136,900)	0.0135%	(0.0000328% - 0.128%)

Notes:

[1] Results are based on the number and percent of systems (and the corresponding population served by those systems) with estimated mean concentrations above the specified level of evaluation.

[2] All percentages are shown to three significant figures. All system values are rounded to the nearest whole system. All population values are rounded to the nearest hundred.

[3] "Credible intervals" are generated to quantify the uncertainty around each estimated probability in the Bayesian analysis of the occurrence data. For further explanation of credible intervals and the Bayesian analysis, please see "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations" (USEPA, 2003d).

[4] Based on the change in the RfD and a 20 percent RSC.

[5] Based on the change in the RfD, a 20 percent RSC, and a risk management factor of 10.

[6] This value does not necessarily reflect the number of systems out of compliance with the current MCL, because these data were collected over the 1993-1997 time period, and because the value represents the estimated mean value over that time period, not the running quarterly average on which compliance is based.

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The results of the detailed occurrence and exposure analysis indicate that less than 0.02 percent of the 19,101 systems sampled in the 16-State cross-section, and less than 0.02 percent of the population served by those 19,101 systems might be affected if EPA were to consider levels as high as 0.03 mg/L to 0.3 mg/L. The current BATs and small system compliance technology for 1,1-dichloroethylene have other beneficial effects (*e.g.*, reduction of other co-occurring contaminants, or other common impurities) in addition to 1,1-dichloroethylene removal. Therefore, if EPA were to consider any of these higher levels, the Agency does not know how many of these public water systems that are currently treating to comply with the current MCL of 0.007 mg/L would be likely to discontinue treatment that is already in place (USEPA, 2002c; USEPA, 2003g).

c. Current Decision. Although there are new health effects data that might support calculation of a less stringent standard for 1,1-dichloroethylene, EPA does not believe a revision to the NPDWR for 1,1-dichloroethylene is appropriate at this time. In making this decision, the Agency considered whether any potential revision to the 1,1-dichloroethylene NPDWR is likely to provide a meaningful opportunity for cost-savings to public water systems and their customers. After consideration of this factor, EPA has decided that any revision to 1,1-dichloroethylene would be a low priority activity for the Agency, and, thus, is not appropriate to revise at this time because of:

- Competing workload priorities;
- The administrative costs associated with rulemaking; and
- The burden on States and the regulated community to implement any regulatory change that resulted.

8. Dichloromethane

One commenter stated that it may be difficult to lower the PQL for dichloromethane below the range of 0.001 to 0.002 mg/L since it is required in a number of EPA methods and therefore is a common laboratory contaminant. Because it is a common laboratory contaminant, the commenter stated that using the MDL for 524.2 and 502.2 does not constitute a reasonable basis for assuming that the PQL can be lower. The commenter stated that none of the existing WS studies had spike samples this low and, in addition, the occurrence data may have been compromised due to laboratory contamination.

EPA Response: The basis for EPA indicating that a lower PQL "may exist" was due to the fact that laboratories had greater than 95 percent laboratory passing rates using a +/−40 percent acceptance window at "known" spike concentrations close to current MCL of 0.005 mg/L. If laboratory contamination due to dichloromethane were a problem, such high passing rates at this value would not be expected. The MDLs for 524.2 and 502.2 were only used with the 10 times MDL multiplier to estimate what the lower value could be. However, EPA does agree that, at this time, the Agency does not have sufficient data to recalculate the PQL for dichloromethane and for this reason, the Agency placed it in the data gap category.

Regarding the occurrence issue, EPA has no data to suggest that high occurrence values were due to false positives from laboratory contamination and the Agency is proceeding on the assumption that State data are accurate unless there is information to the contrary. If laboratory contamination due to dichloromethane does exist, laboratories should be able to identify and discern a contamination issue if they are running laboratory blanks.

9. Di(2-ethylhexyl)adipate (DEHA)

One commenter submitted detailed comments regarding di(2-ethylhexyl)adipate (DEHA). The commenter believed that EPA should consider removing the regulation for DEHA and provided the following reasons:

- The regulation of DEHA in drinking water does not provide any meaningful reduction in the health risk to humans because it is unlikely to cause adverse effects to humans, including reproductive effects, except at very high doses which cannot be attained in drinking water, due to the low water solubility of DEHA.
- The weight of evidence indicates that the peroxisome proliferation mechanism of DEHA rodent carcinogenicity is not relevant to humans. Thus, the MCLG for DEHA should not include an additional 10-fold risk management factor for possible carcinogenicity.
- The legislative history of the 1996 SDWA indicates that Congress envisioned circumstances where relaxation of an MCL would provide the same level of health protection as the existing regulation. Accordingly, if DEHA cannot be deregulated, the commenter believes the MCLG and MCL should be increased.

EPA Response: DEHA was regulated in 1992. Since that time, new studies have become available on the toxicity of DEHA and its metabolites. For this reason, EPA decided to initiate a new health risk assessment of DEHA (67 FR 1212, January 9, 2002 (USEPA, 2002a)). The assessment will include examination of the studies on which the current NPDWR is based, as well as an evaluation of the data provided by this commenter and new studies that have become available since DEHA was regulated. This health risk assessment is planned for completion in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003b)) and is expected to include development of an RfD for non-cancer health effects, as well as an assessment of potential carcinogenicity from oral exposure. At this time, it is premature to predict the outcome of the Agency's assessment. Thus, as discussed in section IV.A.2.a of today's action, the Agency believes that revision to the NPDWR for DEHA is not appropriate at this time. EPA will determine in the future if revision of the MCLG/MCL is warranted. Any revision to the MCLG/MCL will also take into consideration all the new information, including the water solubility of DEHA under various environmental conditions.

As stated by the commenter, the legislative history of the 1996 SDWA Amendments supports EPA's interpretation that the Agency could increase an MCLG and MCL as long as the relaxed standard does not lessen the level of public health protection. However, EPA does not believe, at the present time, that it can demonstrate that deregulating DEHA would maintain the current level of public health protection (see section IV.A.1.c of today's action).

10. Di(2-ethylhexyl)phthalate (DEHP)

The same commenter who submitted comments on DEHA also submitted detailed comments regarding di(2-ethylhexyl)phthalate (DEHP). The commenter felt that EPA should consider removing the regulation for DEHP for a variety of reasons, including the following:

- The regulation of DEHP in drinking water does not provide any meaningful reduction in the health risk to humans.
- The weight of the evidence indicates that the mode of action through which DEHP causes cancer in rodents is not relevant to humans and, thus, the MCLG for DEHP should not be zero. Any MCLG for DEHP should be based on a threshold endpoint and not on cancer. The commenter cited the February 2000 International Agency for Research on Cancer reclassification of DEHP from Group 2B (possibly carcinogenic to humans) to Group 3 (not classifiable as to its carcinogenicity to humans) as justification for recommending that EPA also reconsider its cancer classification.

• The solubility of DEHP in drinking water is well below any concentrations that would pose a risk to humans.
• If DEHP were to be considered for regulation under the statutory requirements of the 1996 SDWA, it would not be regulated.
• The legislative history of the 1996 SDWA indicates that Congress envisioned circumstances where relaxation of an MCL would provide the same level of health protection as the existing regulation. Accordingly, the commenter believes consideration should be given to increasing the MCLG for DEHP based on the new health effects data.
• Reproductive effects from DEHP as observed in rodents do not appear to be relevant for primates and the doses that are associated with effects in animals are well above those that would be experienced for humans exposed through drinking water because of solubility limitations. The commenter also highlighted the findings of the NTP Center for the Evaluation of Risk to Human Reproduction that there was "minimal concern for reproductive or developmental toxicity for the general population, based on estimates of total exposure to DEHP."

EPA Response: Revision of the NPDWR for DEHP is not appropriate at this time because an Agency health risk assessment is currently in process. The assessment is anticipated to be completed in the 2003–2004 time frame (68 FR 5870, February 5, 2003 (USEPA, 2003h)). Advances in understanding differences between the primate and rodent response to DEHP and the body of toxicological data that have become available in the past decade motivated the Agency's re-examination of DEHP and will be fully considered in the reassessment.

Once the Agency assessment is completed, EPA will consider the findings and will determine if there is a compelling reason to review the DEHP NPDWR prior to the next Six-Year Review cycle. As discussed in sections IV.A.1.b and IV.A.2.a of today's action, "revise" versus "not revise" decisions under the Six-Year Review take into consideration occurrence, advances in analytical methods, treatment technologies, available economic information, and other factors.

As stated by the commenter, the legislative history of the 1996 SDWA Amendments supports EPA's interpretation that the Agency could increase an MCLG and MCL as long as the relaxed standard does not lessen the level of public health protection. However, EPA does not believe, at the present time, that it can demonstrate that deregulating DEHP would maintain the current level of public health protection (see section IV.A.1.c of today's action).

11. Fluoride

EPA received three comments on the Agency's decision to place fluoride in the data gap category while the National Academy of Sciences (NAS) examines the toxicological and RSC data published over the last decade. Two of the commenters supported EPA's decision. One of these requested that the NAS concentrate its review on all of the data on the toxicology of fluoride and not just data on the critical skeletal effects. A third commenter requested that EPA not lower the MCL for fluoride from 4 mg/L to 2 mg/L and supported the 1986 EPA decision that dental fluorosis is a cosmetic effect rather than an adverse health effect. The commenter stated that the Public Health Service (PHS) recommended fluoridation level to be used at schools is 3 mg/L. The commenter also stated that if EPA were to lower the MCL, then schools that are currently fluoridating might have a conflict with the PHS recommendations and the EPA MCL.

EPA Response: The National Research Council (NRC) of the NAS has agreed to review the toxicological data on fluoride that have been published since it completed the 1993 study of "Health Effects of Ingested Fluoride" (NRC, 1993), and to examine the data on relative fluoride exposure from drinking water compared to fluoride exposure from the diet and fluoride-containing dental products. Although the Agency indicated in the April 17, 2002, **Federal Register** that new data on bone effects were a reason for initiating the data review (because bone effects were the basis of the present MCLG), the NAS review will look at the new toxicological data for all endpoints. It is anticipated that the NAS review will take about two years to complete. Because of this pending review, revision of the NPDWR for fluoride is not appropriate at this time.

It is therefore premature to make any judgment regarding the NAS findings and whether or not they may lead to a consideration of a change in the MCL. However, PHS recommendations for school fluoridation programs are designed to provide the benefits of fluoridation without increasing the risk for dental fluorosis. The PHS recommends school water fluoridation only if:
• The school has its own source of water;
• The school is not connected to a community water system;
• More than 25 percent of students are not served by a public water system that provides water at levels adequate to protect against dental caries; and
• The students served are kindergarten age or greater.

12. Glyphosate

Two commenters made the statement that, despite continued use of glyphosate in pesticide applications, available data and the Agency's occurrence analysis, which includes a prediction of frequency of occurrence at levels below detection, indicate that glyphosate is not observed in compliance monitoring. One of these commenters stated that the occurrence appeared to be rare (less than 0.1 percent) at concentrations 1,000 times lower than the MCL. In addition, according to the commenters, the cost of analyzing for glyphosate is expensive, since it is a single analyte analysis. Accordingly, the commenters wanted EPA to reconsider the glyphosate standard taking costs and benefits into account. The commenters felt that the data may indicate that a glyphosate standard is inappropriate and does not result in any additional public health protection. Therefore, the commenters recommended EPA pursue data gaps that the Agency would need to fill in order to demonstrate that eliminating the glyphosate standard would not lower public health protection.

EPA Response: EPA is conducting an Agency risk assessment for glyphosate that will update the 1993 OPP assessment. As a part of this process, EPA is considering all the data that have been published or submitted to EPA since the completion of the RED in 1993 (USEPA, 1993). Accordingly, revision of the glyphosate NPDWR is not appropriate at this time due to the pending Agency assessment.

EPA recognizes that some utilities feel that the analysis of glyphosate in drinking water is expensive and that this should be taken into consideration with respect to cost and benefits. This will be considered when EPA evaluates glyphosate in the next review cycle (unless there is a compelling reason to evaluate glyphosate on an accelerated schedule). For the reasons stated in section IV.A.1.c of today's action, EPA does not believe it is appropriate to consider deregulation of glyphosate at this time.

13. Lead and Copper

a. Research Needs. Three commenters acknowledged the Agency's January 2000 revisions to the Lead and Copper Rule (LCR) but stated that the Agency should continue to consider how to make the LCR easier to implement. In particular, they recommended that the following three LCR-related research areas be incorporated into EPA's overall research strategy:

1. How well LCR monitoring results correlate to actual exposure and the effectiveness of the rule in protecting public health.

2. Whether there is a correlation between water quality at indoor and outdoor taps.

3. What effect the ban on lead in fixtures has had on lead levels and whether changes need to be made based on this ban.

The commenters explained their rationale for recommending that the Agency determine if a correlation could be established between indoor and outdoor water quality. They stated that a major weakness of the LCR is that sample integrity may be compromised by allowing customers to collect water samples. If the Agency could establish such a correlation, the LCR could be revised to allow water system operators to collect samples from outdoor taps; thereby removing the need for customer-collected sampling.

EPA Response: EPA recognizes that the LCR is a challenging rule that requires difficult solutions to implement, but continues to believe that the public health objective addressed by the rule is as important and essential today as it was when the rule was first promulgated. Since the Agency promulgated the revisions to the LCR in January 2000 (65 FR 1950, January 12, 2000 (USEPA, 2000)), the Agency has received no significant new information that would support a revision. However, the Agency recognizes that more research would be useful to obtain additional information that could be utilized to address some of the issues associated with the implementation of this rule. For this reason, EPA has revised its rationale for not revising the NPDWR for lead and placed it in the data gaps category. Although the Agency continues to believe that the NPDWR for copper belongs in the risk assessment in process category at the present time, EPA will also consider copper-related risk management and implementation issues as a part of any LCR-related research plans. The Agency is committed to working with stakeholders to support and coordinate identification and prioritization of LCR-related research needs. Until this research is completed, EPA believes it is premature to consider revisions to the LCR; as a result, revision of the LCR is not appropriate at this time.

The Agency believes that understanding the possible correlation between monitoring results and actual rates of exposure and public health protection is a valid issue. However, EPA recognized during the initial regulatory development of the LCR that a significant effort would be necessary to provide a statistically valid number and frequency of samples for an exposure assessment. The Agency thus adopted an alternative approach which specified a monitoring scheme that sought to "* * * assure that systems are performing 'optimal corrosion control' in part by requiring systems to conduct comprehensive tap sampling at homes specifically targeted for their potential to contain elevated levels of lead and copper" (56 FR 26460 at 26514, June 7, 1991 (USEPA, 1991b)). One issue in assessing exposure reduction resulting from the LCR is a determination of an exposure baseline. EPA does not have a lot of data against which to measure changes in exposure that have occurred as a result of rule implementation. For these reasons, EPA believes that there is still insufficient information to change the basic monitoring approach adopted in the original rule, but recognizes that additional research may be useful.

Research on whether a correlation exists between the water quality at indoor taps and water quality at outdoor taps is a very complex issue. Several variables potentially affect whether a reliable correlation exists between indoor and outdoor taps. These variables include: standing time within the system; contact time with the building plumbing; and the content of the interior plumbing. These variables, coupled with the fact that lead levels from building-to-building can be highly site-specific, make a correlation between indoor and outdoor taps difficult to establish. EPA continues to believe that focusing on the point of delivery to the customer most closely links the data collected to the water quality consumed by the customer.

EPA recognizes the commenter's concerns regarding the integrity of samples collected by drinking water customers. To date, however, the Agency has not been able to identify an acceptable alternative to monitoring at the consumer's tap that can produce results equivalent to those obtained at the point of consumption in terms of ensuring adequate public health protection.

Regarding the commenter's third recommendation, EPA will consider this research need as part of the Agency's overall drinking water research planning process.

b. Relaxing the Monitoring Requirements. Three commenters recommended that water systems be allowed to conduct water quality parameter (WQP) monitoring in lieu of continued lead and copper tap monitoring. One of these commenters added that this should be allowed once the system has demonstrated that it does not have a lead problem. This commenter also stated that the new requirements to use lead-free solder and plumbing fixtures should preclude problems with lead. Two commenters noted the difficulty that water systems are having maintaining their current sampling pool because homeowners no longer want to participate in the LCR monitoring program. One of these commenters recommended using WQP results to ensure corrosion control treatment is being adequately maintained and to stop lead and copper monitoring after three to five years. The commenter added that once the system ceases lead and copper monitoring, it can use public education to supplement continuing corrosion control, and can use coupons to demonstrate that corrosion rates meet accepted standards.

EPA Response: While EPA is sensitive to the difficulties associated with the monitoring requirements of the LCR, the Agency is also concerned about the implications of reduced or discontinued monitoring. Significant treatment changes or water chemistry disturbances (such as new water sources, major pH/coagulation changes, disinfectant changes, or seasonal water/treatment changes) can influence the effectiveness of corrosion control, which in turn will require appropriate adjustments of treatment. Current regulations require water systems to continue monitoring lead and copper levels to assure that water quality changes adversely affecting the presence of these contaminants in the drinking water are detected and to assure that appropriate adjustments to maintain optimal corrosion control are made. Proper process control, including water quality and corrosion inhibitor residual concentration monitoring in the distribution system, is the key to making any corrosion control or other treatment work, and assure the continuation of proper water quality. However, EPA recognizes that some changes might be justified in the future based on new, scientifically valid, information and/or research. EPA is considering aspects such as the implications of simultaneous treatment modifications on water quality, including lead and copper control, in its research planning. EPA is not yet able to determine whether the outcome of such research will provide a basis for modifications to the LCR treatment or monitoring requirements. As stated in the response in section IV.B.13.a. of today's action, EPA has placed the LCR in the data gaps category pending the completion of future research.

c. Corrosion Control Treatment Strategy. Two commenters noted concerns regarding the lead and copper corrosion control strategy. One commenter indicated that the LCR should be revised to allow systems to change corrosion control strategies. The commenter stated that considerable development of the corrosion control market has occurred since systems made their initial assessments and implemented corrosion control programs. The commenter felt that currently, the "LCR locks utilities into a given control strategy," when in some instances limited pilot work and ongoing WQP monitoring would allow a system to re-assesses its treatment and implement an alternative corrosion control inhibitor.

The second commenter indicated that the current corrosion control strategies are marginally effective at preventing particulate lead and copper from entering the water supply. The commenter recommended that EPA consider methods for mitigating the release of insoluble components from plumbing fixtures.

EPA Response: The Agency disagrees that the LCR locks utilities into a given control strategy, but feels it is necessary to demonstrate a sound basis for re-assessing and implementing an alternative treatment strategy in the context of the existing regulation. EPA notes that the current regulation provides some flexibility to both States and water systems in the choice of a corrosion control strategy. For example, in response to its own initiative, a request by a water system or other interested party, a State may modify its determination of the optimal corrosion control treatment, among those listed in the Federal regulation, or may modify optimal WQPs if the State determines such changes are necessary to ensure that the system continues to optimize corrosion control treatment (40 CFR 141.82(h)).

The Agency believes that the existing requirements to notify the State when changing a corrosion control strategy remain necessary and appropriate. After they have optimized corrosion control, water systems must notify the State of any treatment changes [7] within 60 days of the change (40 CFR 141.90(a)(3)). The Agency encourages water systems to notify the State prior to making any changes thus allowing the Primacy Agency to review the changes to reduce the potential for detrimental side-effects. In the Agency's experience, changes in treatment, such as (but not restricted to) replacement of high pH treatment with corrosion inhibitor, changes in coagulant and coagulation conditions, changes in disinfection, installation of membrane processes, or introduction of chemically different waters into the distribution system provide potential for detrimental side-effects. Water treatment changes, therefore, should only be done with the greatest care and pilot investigations. While changes to treatment can be made under the existing regulation, systems should conduct additional monitoring (*e.g.*, of lead, copper, and WQPs) until the new treatment is fully implemented and stabilized.

EPA also recognizes that the current LCR may limit flexibility to some extent, particularly in the adoption of new or emerging technologies. The original rule attempted to balance this concern with the need to provide strong public health protection by ensuring that only control strategies of proven effectiveness are adopted. The Agency does not have an adequate basis to revise the treatment requirements at this time but will continue to monitor new developments, including emerging technology. The Agency may consider revisions to the LCR prior to the end of the next Six-Year Review cycle if the Agency receives new, scientifically-valid, information that provides a basis for achieving significant improvement in public health protection or significant cost-savings to utilities and their customers while maintaining current public health protection.

EPA has always recognized that the release of insoluble particulate material containing lead and copper can be an issue in some water systems. While more research may be of interest to improve optimization of corrosion control approaches with respect to this source, EPA expects that evaluations and pilot studies by water systems should include testing and consideration of the relative effectiveness of different treatments towards particulate release in systems for which it is important.

d. Lead Levels in School Drinking Water. One commenter was concerned that the data on lead levels that was analyzed under the Six-Year Review of NPDWR standards may not indicate actual lead contamination of drinking water sources. As an example, the commenter noted that even though Baltimore City is in compliance for lead levels, ⅓ of Baltimore schools are using alternative sources of drinking water due to lead contamination. The commenter expressed concern that since data obtained from schools, such as the data from Baltimore, was not considered in the evaluation of lead contamination in drinking water, the most vulnerable population may not be protected from exposure to lead. The commenter stated that it is time for the Agency to reassess how lead levels are evaluated.

EPA Response: The LCR is designed to address system-wide problems with lead and copper contamination. The rule does not specifically target particular structures, such as schools, but rather contains a monitoring protocol designed to ensure that the overall levels of lead and copper system-wide are minimized. Once optimal treatment is implemented, any remaining problems with elevated lead levels in schools may be due to plumbing, coolers, or other materials in the building. These potential sources of lead in schools are of concern and for this reason are explicitly addressed under the provisions of the Lead Contamination Control Act of 1988 (LCCA) (sections 1461 to 1465 of SDWA). The LCCA directed EPA to publish a guidance manual and testing protocol to assist States and schools in identifying sources and determining the extent of lead contamination in school drinking water and, if necessary, in remedying such contamination. In January 1989, the Agency published and distributed the guidance manual, "Lead in School's Drinking Water," to States and schools (USEPA, 1989). In 1994, the Agency updated and revised the guidance manual entitled "Lead in Drinking Water in Schools and Non-residential Buildings" (USEPA, 1994). A copy of this manual may be obtained from the Safewater website *http://www.epa.gov/safewater/consumer/leadinschools.html*. In addition, the LCCA imposed a ban on the manufacture and sale of water coolers that are not lead free. The LCCA requirements are independent of the NPDWRs and therefore are not addressed under the Six-Year Review process. However, the Agency is continuing to work with schools and States to address problems dealing with lead in school drinking water.

14. Lindane (γ-hexachlorocyclohexane)

In the April 17, 2002, **Federal Register**, the Agency preliminarily placed lindane in the no revision category because a health risk assessment was pending at the time of publication. One commenter stated that

[7] Treatment changes are categorized as changes to any water quality treatment process, including (but not restricted to) disenfection, disinfection by-product removal, and corrosion control.

the RED risk assessment for lindane, issued after publication of the April 17, 2002, **Federal Register**, should be considered in the Agency's review of the NPDWR and expressed concerns regarding the existing regulation. The commenter stated that the current NPDWR is based on an RfD developed in 1988 on the basis of adverse kidney effects and should be revised (USEPA, 1988). The kidney effects were determined to occur through a pathway that is not relevant to human health risk assessment. The commenter stated that the new OPP toxicological assessment has resulted in a significant change to the quantitative dose-response assessment for lindane and that there are no data gaps or uncertainties which would prevent a revision of the NPDWR for lindane at this time.

EPA Response: Since the publication of the April 17, 2002, **Federal Register** and receipt of the comment regarding lindane, the Agency has finalized the risk assessment for lindane and signed the RED on July 31, 2002. The remaining paragraphs in this section include a brief background discussion about the original promulgation of the lindane NPDWR, the results of the appropriate six-year technical reviews and the Agency's revise/not revise decision.

a. Background. EPA published the current NPDWR for lindane on January 30, 1991 (56 FR 3526 (USEPA, 1991a)). The NPDWR established an MCLG and an MCL of 0.0002 mg/L. The Agency based the MCLG on an RfD of 0.0003 mg/kg/day and a cancer classification of C, possible human carcinogen.

b. Technical Reviews. EPA updated the risk assessment on July 31, 2002 (USEPA, 2002b). The new risk assessment established an RfD of 0.0047 mg/kg/day. The Food Quality Protection Act (FQPA) of 1996 provides for an additional safety factor of up to 10-fold, if necessary, in assessing the risks to infants and children to take into account the potential for pre- and post-natal toxicity, and the completeness of the toxicity and exposure databases. This is referred to as the FQPA safety factor. The Agency concluded that an FQPA safety factor of three was required for lindane since there is evidence for increased susceptibility of the young demonstrated in a developmental neurotoxicity and two-generation reproductive toxicity study in rats. The rationale for using an FQPA safety factor of three is detailed in the RED.

In accordance with the 1999 EPA Draft "Guidelines for Carcinogen Risk Assessment" (USEPA, 1999a), the Agency classified lindane as "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." Based on the RfD for lindane of 0.0047 mg/kg/day, the application of the additional FQPA safety factor of three to this RfD, a 20 percent RSC, and a 10-fold risk management factor of suggested evidence of carcinogenicity, EPA used 0.001 mg/L as a level for evaluating the occurrence data.

Analytical or treatment feasibility do not pose any limitations for the current MCL and would not be a limiting factor at the 0.001 mg/L level (USEPA, 2003a; USEPA 2003g). The Agency's review of possible "other regulatory revisions" did not identify any issues that are specific to lindane (USEPA, 2003b).

EPA evaluated the results of the occurrence and exposure analyses for lindane to determine whether possible changes to the standard would be likely to result in a meaningful opportunity for cost-savings to public water systems and their customers (USEPA, 2003d). Table IV–2 shows the results of the detailed occurrence and exposure analysis based on the 16-State cross-section for concentrations of 0.0002 mg/L (the current MCL), and for 0.001 mg/L. Based on the detailed analysis, it appears that lindane is unlikely to occur at concentrations above 0.0002 mg/L in the States used for the cross-section.

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Table IV-2: Lindane Occurrence[1]

Systems[2]			
Level (in mg/L)	16-State Cross-Section - Total Systems with Data	Estimated # of Systems > Level Evaluated (credible intervals)[3,4]	Estimated % of Systems > Level Evaluated (credible intervals)[3]
Level Evaluated 0.001	16,098	0 (0-0)	0.000% (0.000% - 0.000%)
Current MCL 0.0002	16,098	0 (0-0)	0.000% (0.000% - 0.000%)

Population Served by Systems[2]			
Level (in mg/L)	16-State Cross-Section - Total Population Served by Systems with Data	Estimated Population Served by Systems > Level Evaluated (credible intervals)[3]	Estimated % of Population Served by Systems > Level Evaluated (credible intervals)[3]
Level Evaluated 0.001	99,942,600	0 (0-0)	0.000% (0.000% - 0.000%)
Current MCL 0.0002	99,942,600	0 (0-0)	0.000% (0.000% - 0.000%)

Notes:

[1] Results are based on the number and percent of systems (and the corresponding population served by those systems) with estimated mean concentrations above the specified level of evaluation.

[2] All percentages are shown to three significant figures. All system values are rounded to the nearest whole system. All population values are rounded to the nearest hundred.

[3] "Credible intervals" are generated to quantify the uncertainty around each estimated probability in the Bayesian analysis of the occurrence data. For further explanation of credible intervals and the Bayesian analysis, please see "Occurrence Estimation Methodology and Occurrence Findings Report for the Six-Year Review of Existing National Primary Drinking Water Regulations" (USEPA, 2003d).

[4] This value does not necessarily reflect the number of systems out of compliance with the current MCL, because these data were collected over the 1993-1997 time period, and because the value represents the estimated mean value over that time period, not the running quarterly average on which compliance is based.

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The results of the detailed occurrence and exposure analysis indicate that few, if any, of the 16,098 systems sampled in the 16-State cross-section might be affected if EPA were to consider levels as high as 0.001 mg/L. The current BATs and small system compliance technology for lindane have other beneficial effects (*e.g.*, reduction of other co-occurring contaminants, or other common impurities) in addition to lindane removal. Therefore, if EPA were to consider a higher level, the Agency does not know how many of these public water systems that are currently treating to comply with the current MCL of 0.0002 mg/L would be likely to discontinue any treatment that is already in place (USEPA, 2002c; USEPA, 2003g).

c. *Current Decision*. Although there are new health effects data that might support calculation of a less stringent standard for lindane, EPA does not believe a revision to the NPDWR for lindane is appropriate at this time. In making this decision, the Agency considered whether any potential revision to the lindane NPDWR is likely to provide a meaningful opportunity for cost-savings to public water systems and their customers. After consideration of this factor, EPA has decided that any revision to lindane would be a low riority activity for the Agency, and, hus, is not appropriate to revise at this ie because of:

• Competing workload priorities;
• The administrative costs associated with rulemaking; and
• The burden on States and the regulated community to implement any regulatory change that resulted.

15. Simazine

One commenter agreed that simazine should be addressed after the risk assessment is completed in 2003 or 2004. The commenter requested that the Office of Water (OW) work closely with the OPP on the risk assessment at that time. The commenter also recommended that OW address the revision of the existing simazine NPDWR before the next review cycle year, scheduled for 2008. The commenter believes the extensive mammalian toxicology database, submitted as part of the Triazine Special Review, can be used in this process.

EPA Response: OW has been coordinating with OPP for the revision of the atrazine and simazine risk assessments. Once the simazine risk assessment is completed, EPA will determine whether a compelling reason sts to consider review of the simazine DWR on an accelerated schedule.

C. What Comments Did EPA Receive Regarding the Review of Implementation-Related Issues for Chemical NPDWRs?

Several commenters recommended that EPA ensure consistent application of rules by making rules more consistent with respect to monitoring frequency, triggers for increased monitoring, criteria for returning to routine monitoring, and criteria for reducing sample requirements. In addition, commenters suggested that the Agency review possible ways for reducing the reporting burden on States, which could free up State resources currently used to implement rules.

One commenter was concerned about monitoring and reporting issues in conjunction with CMR. The commenter felt that EPA should not miss an opportunity to relieve some of the unnecessary confusion that the monitoring requirements of Phase II and V have created. This confusion includes issues such as, what a detection is and what the monitoring requirements are for systems in States without a waiver program. EPA was encouraged to provide this consistency as much as possible, including using the standard monitoring framework to allow States and water systems to more easily understand rule requirements and reduce the need for States to update their data management systems.

One commenter said EPA should ensure consistent application of rules by determining whether or not chronic contaminants should be regulated at non-transient non-community water systems (NTNCWSs), and review existing NPDWRs to ensure that rules are applied consistently. Another commenter recommended that the compliance language for the synthetic organic chemicals (SOCs) and volatile organic chemicals (VOCs) in the Final Arsenic Rule (66 FR 6975, January 22, 2001 (USEPA, 2001)) be adopted for the inorganic chemicals (IOCs), and that systems not be considered in violation of the MCL until it has completed one year of quarterly samples.

EPA Response: The Agency agrees that consistency across regulations is desirable to the extent that it does not jeopardize public health protection or the environment.

As part of the Advanced Notice of Proposed Rulemaking for CMR (62 FR 36100, July 3, 1997 (USEPA, 1997a)), EPA considered some of the issues raised by the commenters. However, during the comment period for the CMR, stakeholders generally indicated that the existing monitoring framework was sufficient. Most State commenters indicated that it would be too burdensome to adopt CMR. As a result, the Agency decided to take no further action on the CMR. However, the Agency established a standardized monitoring framework which applies to all of the regulated chemical and radiological contaminants (except lead and copper). The new chemical and radiological rules that EPA has promulgated (*e.g.*, arsenic and radionuclides) are coordinated with the standardized monitoring framework. The Agency made special efforts to ensure that the reduced monitoring periods are in line with the 3-year compliance periods in the standardized monitoring framework.

To assist States with understanding rule requirements, the Agency conducted a series of Phase II/V training in 2001. The training provided information to help States make informed decisions about reducing quarterly monitoring requirements. With respect to reduced monitoring, States currently have the flexibility to reduce the frequency of monitoring and/or to waive sampling requirements for any given contaminant after minimum criteria are met to demonstrate that the system is reliably and consistently below the MCL and/or not vulnerable to contamination.

NTNCWSs are traditionally regulated for chronic contaminants. However, through an alternative mechanism, the Agency is currently evaluating risk and exposure as they pertain to NTNCWS monitoring requirements. This review will not be completed in time for this Six-Year Review process. Until all the issues have been identified and specific options have been formulated, it will not be clear if a revision to regulations is indicated.

EPA intends to consistently implement compliance determination provisions for IOCs, SOCs, and VOCs for all NTNCWSs and community water systems, as described in the preamble to the Final Arsenic Rule (66 FR 6975 at 6990, January 22, 2001 (USEPA, 2001)). The rule makes compliance determinations based on a running annual average. The clarifications to compliance determinations for SOCs, IOCs, and VOCs are based on the average of the initial MCL exceedance and any subsequent State-required confirmation samples. States have the flexibility to require confirmation samples and more frequent monitoring, in addition to required quarterly samples. The average of the exceedance and confirmation sample constitutes the first quarterly sample. Compliance with the MCL is based on the average of the first quarterly sample and three additional samples over a period of one year, unless any one quarterly sample would cause the running annual average to exceed the MCL. Then the system is out of compliance immediately.

D. What Comments Did EPA Receive on the Total Coliform Rule?

Several commenters addressed the TCR. Several commenters raised several issues relating to monitoring. Some contended that routine monitoring should be focused on critical locations in the distribution system, rather than on the current requirement to monitor all parts of the distribution system. They also urged EPA to allow the use of dedicated sampling taps. Some commenters argued for allowing a finished water storage reservoir as a routine monitoring site. Two commenters urged EPA to focus on E. coli as the measure of water quality in the distribution system, rather than on total coliforms. In addition to routine monitoring, a few commenters addressed the topic of repeat samples after a total coliform-positive sample. One commenter, for example, urged EPA to eliminate the requirement to take upstream and downstream repeat samples after a total coliform-positive sample. Environmental groups urged EPA to strengthen the TCR and other ıles that protect against pathogens, and xhorted EPA not to ease the TCR ırden such that public health is ompromised.

EPA Response: EPA's announcement in the April 17, 2002, **Federal Register** was only intended to discuss the Agency's intent to begin the process for revising the TCR. EPA will consider the commenters' suggestions as part of the revision process. As stated in the April 17, 2002, **Federal Register**, the Agency plans to consider revisions to the TCR with new requirements for ensuring the integrity of distribution systems. The Agency remains committed to obtaining input from stakeholders as part of the rule development process. EPA agrees with the comment that public health should not be compromised, and will consider only those revisions that will assure public health protection.

E. What Comments Did EPA Receive on Research Needs?

Commenters found that EPA's information on potential research resulting from the review of NPDWRs would be better represented by a summary of research needs that were identified by the Agency. Commenters felt that this summary is important to inform future regulatory decisions. nmenters also suggested additional ...rch needs that had not been identified by EPA in its preliminary review.

EPA Response: EPA agrees that the identification of research needs is an important component of the review of NPDWRs. Research findings may support future reviews and/or revisions to NPDWRs.

The Agency is considering research needs that it identified as part of the review as well as those suggested by commenters. EPA will continue to identify areas where data are lacking. Dialogue with industry and other groups, including those that sponsor or conduct research on priority areas, would be beneficial to the drinking water program. Collaboration in sponsoring studies can provide multiple benefits.

There are two research needs associated with the Six-Year Review that are being addressed through mechanisms external to EPA. The National Research Council of the National Academy of Sciences is conducting an assessment of recent data on fluoride health effects. In addition, the National Toxicology Program is conducting a study on chromium VI toxicity. Both of these research efforts are discussed in the April 17, 2002, **Federal Register** announcement of EPA's preliminary revise/not revise decisions. The current review identified several general and specific areas of potential research related to treatment. The treatment-related research areas are briefly discussed in the Treatment Feasibility Document (USEPA, 2003g).

EPA is currently in the process of examining whether specific research needs exist within each of the Six-Year Review areas of regulatory consideration (*i.e.*, health effects, analytical methods, treatment, implementation, and occurrence/exposure). Some of the research needs identified during the Six-Year Review effort will be discussed in the context of the Multi-Year Plan (MYP) for drinking water. The MYP describes the EPA Office of Research and Development's fiscal year 2003 to 2010 research program to support the regulatory development activities of the EPA Office of Water. EPA plans to make this document available to the public in 2003.

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USEPA. 2003f. Six-Year Review—Chemical Contaminants—Health Effects Technical Support Document. EPA 822–R–03–008. Final. June 2003.

USEPA. 2003g. Water Treatment Technology Feasibility Support Document for Chemical Contaminants; In Support of EPA Six-Year Review of National Primary Drinking Water Regulations. EPA 815–R–03–004. Final. June 2003.

USEPA. 2003h. Integrated Risk Information System (IRIS); Announcement of 2003 Program; Request for Information and Announcement of Workshop; Notice. Federal Register. Vol. 68, No. 24. p. 5870, February 5, 2003.

Dated: July 11, 2003.

Linda J. Fisher,

Acting Administrator.

[FR Doc. 03–18152 Filed 7–17–03; 8:45 am]

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Reference Dose for Chronic Oral Exposure (RfD)

You will need Adobe Reader to view some of the files on this page. See EPA's PDF page to learn more.

Note: A TOXICOLOGICAL REVIEW is available for this chemical in Adobe PDF Format (72 Pages, 531 Kbytes). Similar documents can be found in the List of Available IRIS Toxicological Reviews.

Links to specific pages in the toxicological review are available throughout this summary. To utilize this feature, your Web browser and Adobe program must be configured properly so the PDF displays within the browser window. If your browser and Adobe program need configuration, please go to EPA's PDF page for instructions.

0039

1,1-Dichloroethylene (1,1-DCE); CASRN 75-35-4; 08/13/02

Health assessment information on a chemical substance is included in IRIS only after a comprehensive review of chronic toxicity data by U.S. EPA health scientists from several Program Offices, Regional Offices, and the Office of Research and Development. The summaries presented in Sections I and II represent a consensus reached in the review process. Background information and explanations of the methods used to derive the values given in IRIS are provided in the Background Documents.

STATUS OF DATA FOR 1,1-Dichloroethylene (1,1-DCE)

File First On-Line 01/30/1987

Category (section)	**Status**	**Last Revised**
Oral RfD Assessment (I.A.)	on-line	08/13/2002*
Inhalation RfC Assessment (I.B.)	on-line	08/13/2002*
Carcinogenicity Assessment (II.)	on-line	08/13/2002*

*A comprehensive review of toxicological studies was completed (05/27/05) - please see sections I.A.6., I.B.6., and II.D.2. for more information.

_I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

_I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — 1,1-Dichloroethylene (1,1-DCE)
CASRN — 75-35-4
Last Revised — 08/13/2002

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

This summary replaces the summary dated 04/01/1989. This RfD differs from the previous EPA value of 0.009 mg/kg-day. The previous EPA evaluation used the same study but considered the lowest exposure of 9 mg/kg-day in female rats as a LOAEL for minimal hepatocellular fatty change and minimal hepatocellular swelling and applied a total uncertainty factor (UF) of 1000 (10 for LOAEL-to-NOAEL extrapolation, 10 for interspecies extrapolation, and 10 for human variability). EPA no longer considers hepatocellular swelling, in the absence of other effects such as increased liver enzymes in the serum, as biologically significant in this bioassay. The increased incidence of midzonal fatty change at 9 mg/kg-day in female rats is not statistically significant. The NOAEL in this bioassay is 9 mg/kg-day. In addition, the present evaluation uses benchmark dose (BMD) methodology and calculates a $BMDL_{10}$ for midzonal fatty change in female rats.

__I.A.1. Oral RfD Summary

Critical Effect	Experimental Doses*	UF	MF	RfD
Liver toxicity (fatty change)	NOAEL: 9 mg/kg-day LOAEL: 14 mg/kg-day			
Rat chronic drinking water study	$BMDL_{10}$: 4.6 mg/kg-day	100	1	5E-2 mg/kg-day
Quast et al. (1983)				

*Conversion Factors and Assumptions — The authors provided the exposure data from the bioassay based on measured drinking water consumption.

__I.A.2. Principal and Supporting Studies (Oral RfD)

Quast et al. (1983) conducted a 2-year chronic toxicity and carcinogenicity study of 1,1-DCE in Sprague-Dawley rats (6–7 weeks old). The control group comprised 80 rats of each sex, and each exposed group comprised 48 rats of each sex. The 1,1-DCE was incorporated in the drinking water of the rats at nominal concentrations of 0, 50, 100, or 200 ppm. The time-weighted average exposure over the 2-year period was 7, 10, or 20 mg/kg-day for males and 9, 14, or 30 mg/kg-day for females. Rampy et al. (1977) also reported some of the data. Humiston et al. (1978) reported more detailed data. No significant differences were observed among the groups in appearance and demeanor, mortality, body weight, food consumption, water consumption, hematology, urinalysis, clinical chemistry determinations, organ weights, or organ to body weight ratios. After 1 year on study, there was no depletion of the nonprotein sulfhydryl levels in the liver or the kidneys (Rampy et al., 1977).

The only treatment-related effect observed in rats was minimal hepatocellular midzonal fatty change and hepatocellular swelling. At the termination of the study, male rats showed increased incidence of minimal hepatocellular fatty change (control, 14/80; 50 ppm, 5/48; 100 ppm, 13/48; 200 ppm, 19/47) and minimal hepatocellular swelling (control, 0/80; 50 ppm, 1/48; 100 ppm, 2/48; 200 ppm, 3/47). The changes were statistically significant ($p<0.05$) only in the 200 ppm group. At the termination of the study, female rats showed an increased incidence of minimal hepatocellular fatty change (control, 10/80; 50 ppm, 12/48; 100 ppm, 14/48; 200 ppm, 22/48; statistically significant [$p<0.05$] at 100 and 200 ppm) and minimal hepatocellular swelling (control, 3/80; 50 ppm, 7/48; 100 ppm, 11/48; 200 ppm, 20/48; statistically significant [$p<0.05$] in all groups). No exposure-related neoplastic changes occurred at any exposure. No hepatocellular necrosis was evident at any exposure. Based on the minimal nature of the hepatocellular swelling reported by the authors and no change in liver weight, no change in clinical chemistry measurements diagnostic for liver damage, and no other indication of abnormal liver function, the hepatocellular swelling is not considered biologically significant or an adverse effect in this study. The statistically significant hepatocellular midzonal fatty change, however, is considered a minimal adverse effect in this study. Accordingly, the NOAEL in male rats is 10 mg/kg-day and the LOAEL is 20 mg/kg-day; the NOAEL in female rats is 9 mg/kg-day and the LOAEL is 14 mg/kg-day. A BMD analysis was conducted for the results in female rats. In female rats, the BMD_{10} is 6.6 mg/kg-day and the $BMDL_{10}$ is 4.6 mg/kg-day.

A three-generation study by Nitschke et al. (1983), described in Section I.A.4, corroborated the results of Quast et al. (1983).

The National Toxicology Program conducted 104-week chronic toxicity and carcinogenicity studies of 1,1-DCE in male and female F344 rats (200 of each sex, 9 weeks old) by gavage in corn oil at 0, 1, or 5 mg/kg-day (NTP, 1982). There were no significant differences in survival, clinical signs, or body weight as compared with controls for any group, suggesting that the maximum tolerated dose was not achieved. The results of histopathological examination indicated chronic renal inflammation in male rats (26/50, 24/48, 43/48) and female rats (3/49, 6/49, 9/44). The increase was statistically significant only in males. As this lesion commonly occurs in male rats (Kluwe et al., 1984, 1990), it is not considered biologically significant in this study. The NOAEL in this study 5 is mg/kg-day (the highest exposure tested).

NTP also conducted 104-week chronic toxicity and carcinogenicity studies of 1,1-DCE in male and female B6C3F_1 mice (50 of each sex in each group, 9 weeks old) by gavage in corn oil at 0, 2, or 10 mg/kg (NTP, 1982). There were no significant differences in survival, clinical signs, or body weight in any group. The only noncancer effect observed by histopathological examination was necrosis of the liver (male: 1/46; 3/46; 7/49; female: 0/47; 4/49; 1/49). The effect was not statistically significant at either exposure ($p=0.6$ and 0.06 at the mid- and high-exposure levels in males using a two-tailed test, respectively). In male and female mice the NOAEL is 10 mg/kg-day (the highest exposure tested). The BMD_{10} is 7.8 mg/kg-day and the $BMDL_{10}$ is 4.1 mg/kg-day. This study was not used to derive the RfD because the gavage route of exposure will affect the pharmacokinetics of 1,1-DCE and the exposure-response relationship.

__I.A.3. Uncertainty and Modifying Factors (Oral RfD)

UF — 100

The critical effect is liver toxicity (fatty change) in rats, with a $BMDL_{10}$ of 4.6 mg/kg-day. Although this minimal effect might not be considered adverse—as there is no evidence of a functional change in the liver in rats exposed and glutathione levels are not reduced in this bioassay—the $BMDL_{10}$ was used to derive the RfD, because limiting exposure to the $BMDL_{10}$ will protect the liver from more serious damage (fatty liver or necrosis) that could compromise liver function. Individual UFs of 10 each were used for interspecies extrapolation and intraspecies variability because there were no applicable data to justify departure from the default values. Derivation of the RfD from the $BMDL_{10}$ for the minimal fatty change in the liver does not require an effect-level extrapolation. This conclusion is based on the minimal nature of the fatty change and its questionable biological significance because of the absence of any observable functional deficit in the liver. A subchronic-to-chronic extrapolation factor was not applied because the study exposed the animals for 2 years. A database UF is not applied because the database is considered complete. A number of long-term bioassays in rodents by the oral or inhalation route show that liver toxicity is the critical effect. There is no chronic bioassay in a nonrodent mammal. However, there are 90-day bioassays in several species (rats, mice, dogs, guinea pigs, rabbits, and monkeys) that suggest similar exposure-response relationships across species. Therefore, the lack of a chronic bioassay in a nonrodent mammal is not considered a data gap. There are no focused studies on neurotoxicity, but there is no indication from chronic, reproductive, and developmental bioassays in rats and mice by oral or inhalation exposure that neurotoxicity in an important toxic endpoint. No long-term studies have evaluated immunotoxicity in laboratory animals by any route of exposure. The existing bioassays, however, provide no suggestion that immunotoxicity is a critical effect. EPA does not consider these data gaps compelling enough to require application of a database UF.

MF = 1.

__I.A.4. Additional Studies/Comments (Oral RfD)

NTP (1982) conducted a study in male and female F344 rats (10 of each sex, 9 weeks old) administered 1,1-DCE by gavage in corn oil at 0, 5, 15, 40, 100, or 250 mg/kg. Animals were exposed five times per week for 13 weeks. Representative tissues from animals receiving 250 mg/kg and from control animals were examined microscopically. Livers from all groups were examined. Three female rats receiving 250 mg/kg died during the first week of the study. No other rats died. The mean body weight was depressed 13% for male rats receiving 250 mg/kg as compared with controls. Mean body weight in other groups was comparable. Only the liver showed effects attributed to 1,1-DCE. At 250 mg/kg, the three female rats that died showed severe centrilobular necrosis. Minimal to moderate hepatocytomegaly was seen in the rest of the rats at 250 mg/kg. Minimal to mild hepatocytomegaly was seen in 6/10 male rats and 3/10 female rats that received 100 mg/kg. No biologically significant changes were observed in rats that received 40 mg/kg or less. The NOAEL in this study is 40 mg/kg (equivalent to 28.5 mg/kg-day); the LOAEL is 100 mg/kg (equivalent to 71.4 mg/kg-day).

NTP (1982) conducted a study in male and female $B6C3F_1$ mice (10 of each sex, 9 weeks old) administered 1,1-DCE by gavage in corn oil at 0, 5, 15, 40, 100, or 250 mg/kg. Animals were exposed five times per week for 13 weeks. Representative tissues from mice receiving 100 and 250 mg/kg and from control animals were examined microscopically. Livers from all groups were also examined. Survival was 20/20, 19/20, 19/20, 19/20, 15/20, and 1/20 at 0, 5, 15, 40, 100, and 250 mg/kg, respectively. At 100 mg/kg there was a decrease in mean body weight in males (14%) but not in females. No change in mean body weight was observed at lower exposures. Only the liver showed effects attributed to 1,1-DCE. Centrilobular necrosis of the liver was observed in 5/10 males and 5/10 females that received 250 mg/kg and 2/10 males and 2/10 females that received 100 mg/kg. No biologically significant changes in the liver occurred in mice receiving 40 mg/kg or less. The NOAEL in this study is 40 mg/kg (adjusted to a continuous daily exposure of 28.6 mg/kg-day); the LOAEL is 100 mg/kg (adjusted to a continuous daily exposure of 71.4 mg/kg-day).

Quast et al. (1983) conducted a study in beagle dogs (four per group, 8 months old) administered 1,1-DCE by gavage in peanut oil at 0, 6.25, 12.5, or 25 mg/kg-day for 97 days. No significant differences were observed among groups in appearance and demeanor, mortality, body weight, food consumption, hematology, urinalysis, clinical chemistry determinations, organ weights, and organ-to-body-weight ratios. No exposure-related gross or histopathological changes were present in tissues. There was no depletion of the nonprotein sulfhydryl levels in the liver or kidneys. The NOAEL in this study is 25 mg/kg-day (the highest exposure tested).

Reproductive and Developmental Studies

Nitschke et al. (1983) evaluated the reproductive and developmental toxicity of 1,1-DCE in Sprague-Dawley rats. Three generations of the test animals were exposed to drinking water containing nominal 1,1-DCE concentrations of 0 (initially 15 males and 30 females), 50, 100, or 200 ppm (initially 10 males and 20 females at each exposure). The authors provided no information on water consumption. This study was a companion study to Quast et al. (1983) and used the same concentrations of 1,1-DCE in drinking water; in Quast et al. (1983) the average exposure to females was 9, 14, or 30 mg/kg-day. After 100 days of exposure, the rats were mated.

In this three-generation study, there were no biologically significant changes in fertility index, in average number of pups per litter, in average body weight of pups, or in pup survival at any exposure. Neonatal survival was decreased from concurrent control values in the f_2 and f_{3a} litters of dams ingesting 1,1-DCE from drinking water. The survival indices, however, were within the range of control values for this strain of rats in this laboratory. The authors attributed the decreased survival index in f_2 to increased litter size at birth in dams exposed to 1,1-DCE. The apparent effect seen in the f_{3a} litters was not repeated in subsequent matings of the same adults to produce either the f_{3b} or the f_{3c} litters. The authors attributed the decreased survival in the f_{3a} litters as being due to chance.

Histopathological examination of tissues of rats exposed to 1,1-DCE in the drinking water in utero, during lactation, and postweaning revealed slight hepatocellular fatty change and an accentuated hepatic lobular pattern of a reversible nature in the adult rats (data not reported, but the observation is consistent with that reported by Quast et al. [1983] in a chronic bioassay). These effects were observed in the 100 and 200 ppm groups in the F_1 generation and in all groups of the F_2 generation. The authors did not present incidence data and did not report statistical analysis. Exposure to 1,1-DCE in drinking water at concentrations causing mild, dose-related changes in the liver did not affect the reproductive capacity of rats through three generations that produced six sets of litters. The NOAEL for reproductive and developmental toxicity in this study is 200 ppm for exposure to 1,1-DCE in drinking water (the highest exposure tested and about 30 mg/kg-day).

Murray et al. (1979) evaluated the developmental toxicity of 1,1-DCE administered in drinking water at 0 (27 animals) or 200 ppm (26 animals) to pregnant Sprague-Dawley rats (body weight 250 g). Rats were exposed on gestation days 6–15 at 40 mg/kg-day. No teratogenic effects were seen in the embryos using standard techniques for soft and hard tissue examination, and there was no evidence of toxicity to the dams or their offspring. The NOAEL for developmental toxicity in this study is 40 mg/kg-day (the highest exposure tested).

Dawson et al. (1993) evaluated the ability of 1,1-DCE administered in drinking water at 110 ppm or 0.15 ppm to female Sprague-Dawley rats (body weight 250 g) to induce fetal cardiac changes. Rats were administered 110 ppm 1,1-DCE for 61 days before mating or for 48 days before mating and for 20 days during gestation. Other rats were administered 0.15 ppm 1,1-DCE for 82 days before mating or for 56 days before mating and for 20 days during gestation. The dams were killed on gestational day 22 and the gravid uterus was removed and examined. There was no effect on maternal weight gain, average resorption sites (sites where development began but resorption later occurred), or average implantation sites (sites that did not appear to develop beyond implantation and contained a metrial gland only). No increase in the incidence of cardiac changes occurred when dams were exposed only before mating. There was, however, a statistically significant increase (p<0.01) in the percent of fetuses with cardiac changes (atrial septal, mitral valve, and aortic valve changes) when the dams were exposed before mating and during gestation. The incidence was control, 7/232 (3%); 0.15 ppm, 14/121 (12%); and 110 ppm, 24/184 (13%).

This statistical analysis was based on total occurrence of affected fetuses. Because the exposure was to the dam and not to individual fetuses, a nested statistical analysis is preferred. Such an analysis takes into account the correlation among fetuses within a litter and the possible nesting of effects within litters. This analysis has not been conducted because all the necessary data are not available. The author provided additional data to resolve typographical errors in the exposure information for each group and to clarify the number of affected litters and number of fetuses per litter affected (letter from Brenda Dawson, University of Auckland, New Zealand, to Robert Benson, U.S. EPA, January 24, 2001). The exposure to dams before and during pregnancy was 0, 0.02, or 18 mg/kg-day in the control, 0.15 ppm, and 110 ppm groups, respectively. The number of affected litters was 5/21 (24%), 8/11 (73%), and 13/17 (76%). The mean number of affected fetuses per litter for affected litters only was 1.40 (13% of the fetuses in the litter), 1.75 (16% of the fetuses in the litter), and 1.85 (17% of the fetuses in the litter). The mean number of affected fetuses per litter for all litters was 0.33 (3% of the fetuses in the litter), 1.27 (12% of the fetuses in the litter), and 1.41 (13% of the fetuses in the litter).

Dawson et al. (1993) did a much more thorough evaluation of alterations in cardiac development than is done in standard developmental toxicity testing protocols. There is no experience with the background rates or the functional significance of such alterations from other studies or laboratories. The incidence of alterations in control fetuses (3% of all fetuses, 24% of all litters, and 1.40 affected fetuses per affected litter) suggests a high background incidence. The authors reported that examinations were done blind to the treatment group, so the data are presumed not to be affected by observer bias.

There is no demonstrated exposure-response relationship in Dawson et al. (1993). A 900-fold increase in exposure did not produce a significant, increase in response in any measure of effect. The cardiac changes are of questionable biological significance, as there were no biologically significant effects reported on growth and survival in the three-generation study (Nitschke et al., 1983). No cardiac effects were reported in a prenatal developmental study (Murray et al., 1979); however, in this study exposure to 1,1-DCE did not occur throughout pregnancy. The pharmacokinetics of 1,1-DCE make it biologically implausible that the cardiac changes were causally associated with exposure to 1,1-DCE. The exposures used in Dawson et al. (1993) are below the level of saturation of CYP2E1 in the rat liver. Essentially all of the 1,1-DCE administered to the dams will be metabolized in the liver and will react with glutathione or macromolecules in the liver. (See the discussion and references in Section 3.) Therefore, it is extremely unlikely that any significant amount of 1,1-DCE or any toxic metabolite will be in the fetal compartment. CYP2E1 is not expressed in fetal liver but begins to be expressed shortly after birth (Cresteil, 1998).

EPA is not aware of any information on the expression of CYP2E1 in fetal cardiac tissue. Cardiac tissue, however, is not generally considered to be a tissue with significant potential for metabolism of xenobiotics. For these reasons EPA cannot conclude that the cardiac changes are caused by exposure to 1,1-DCE. It would be helpful if more definitive studies with a greater range of exposures were conducted to determine the cause and biological significance of the cardiac changes apparently associated with exposure to 1,1-DCE during the period of cardiac organogenesis.

For more detail on Susceptible Populations, exit to the toxicological review, Section 4.7 (PDF).

I.A.5. Confidence in the Oral RfD

Study — High
Database — Medium
RfD — Medium

The overall confidence in this RfD assessment is medium. The principal study (Quast, 1983) was well conducted, with an adequate number of animals and appropriate evaluation of a wide variety of endpoints. This study is supported by an additional bioassay in rats (NTP, 1982) and a three-generation reproductive and developmental study showing consistent effects in the liver. A three-generation reproductive study and several bioassays show that reproductive and developmental toxicity are not critical effects. One developmental study, however, shows variations in cardiac morphology that have appear to have little or no physiological consequence. There are no focused studies on neurotoxicity, but there are no indications from chronic, reproductive, or developmental bioassays in rats and mice by oral or inhalation exposure that neurotoxicity is an important toxic endpoint. No long-term studies have evaluated immunotoxicity in laboratory animals by any route of exposure. The existing bioassays, however, provide no suggestion that immunotoxicity is a critical effect. Accordingly, the database is given a medium confidence, but no additional UF is considered necessary.

For more detail on Characterization of Hazard and Dose Response, exit to the toxicological review, Section 6 (PDF).

__I.A.6. EPA Documentation and Review of the Oral RfD

Source Document — Toxicological Review of 1,1-Dichloroethylene (2002)

This assessment was peer reviewed by external scientists. Their comments have been evaluated carefully and incorporated in finalization of this IRIS Summary. A record of these comments is included as an appendix to the Toxicological Review of 1,1-Dichloroethylene. ***To review this appendix, exit to the toxicological review, Appendix A, Summary of and Response to External Peer Review Comments (PDF).***

Other EPA Documentation — This assessment replaces previous assessments (U.S. EPA, 1985a,b).

Agency Consensus Date — 06/07/2002

A comprehensive review of toxicological studies published through May 2005 was conducted. No new health effects data were identified that would be directly useful in the revision of the existing RfD for 1,1-Dichloroethylene (1,1-DCE) and a change in the RfD is not warranted at this time. For more information, IRIS users may contact the IRIS Hotline at hotline.iris@epa.gov or 202-566-1676.

__I.A.7. EPA Contacts (Oral RfD)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or hotline.iris@epa.gov (internet address).

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_I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — 1,1-Dichloroethylene (1,1-DCE)

CASRN — 75-35-4
Last Revised — 08/13/2002

The inhalation Reference Concentration (RfC) is analogous to the oral RfD and is likewise based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. The inhalation RfC considers toxic effects for both the respiratory system (portal-of-entry) and for effects peripheral to the respiratory system (extrarespiratory effects). It is generally expressed in units of mg/cu.m. In general, the RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure of the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Inhalation RfCs were derived according to the Interim Methods for Development of Inhalation Reference Doses (EPA/600/8-88/066F August 1989) and subsequently, according to Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (EPA/600/8-90/066F October 1994). RfCs can also be derived for the noncarcinogenic health effects of substances that are carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

The previous EPA evaluation did not derive an RfC.

__I.B.1. Inhalation RfC Summary

Critical Effect	Experimental Doses*	UF	MF	RfC
Liver toxicity (fatty change)	$NOAEL_{HEC}$: 17.7 mg/m^3 $LOAEL_{HEC}$: 53.2 mg/m^3			
Rat chronic inhalation study Quast et al. (1986)	$BMCL_{10HEC}$: 6.9 mg/m^3	30	1	2E-1 mg/m^3

*Conversion Factors and Assumptions — The NOAEL from the chronic bioassay is 25 ppm, where the exposure was for 6 hrs/day, 5 days/wk. The conversion factor is 1 ppm = 3.97 mg/m^3. The human equivalent concentration (HEC) was calculated using the equation for a category 3 gas (U.S. EPA, 1994). The blood:gas partition coefficient in the rat is 5 (D'Souza and Andersen, 1988). No useable data are available on the blood:gas coefficient in humans. Accordingly the default value of 1 is used for the ratio of these coefficients.

$NOAEL_{HEC} = NOAEL_{adj} \times (H_{b/g})_A/(H_{b/g})_H = 25 \text{ ppm} \times 6/24 \times 5/7 \times 1 \times 3.97 = 17.7 \text{ mg/m}^3$
$BMCL_{HEC} = BMCL_{adj} \times (H_{b/g})_A/(H_{b/g})_H = 9.8 \text{ ppm} \times 6/24 \times 5/7 \times 1 \times 3.97 = 6.9 \text{ mg/m}^3$

__I.B.2. Principal and Supporting Studies (Inhalation RfC)

Quast et al. (1986) and Rampy et al. (1977) reported results from studies that exposed male and female Sprague-Dawley rats (Spartan substrain, 86 animals/group) to 1,1-DCE by inhalation 6 hrs/day, 5 days/wk, for up to 18 months. Interim sacrifices occurred at 1, 6, and 12 months. Rats were exposed to 1,1-DCE concentrations of 10 ppm and 40 ppm for the first 5 weeks of the study. Because of the absence of observable treatment-related effects among rats sacrificed after 1 month of exposure, the concentrations were increased to 25 and 75 ppm. Exposures were continued at these concentrations through the 18th month of the study. The surviving animals were then held without exposure to 1,1-DCE until 24 months. Cytogenetic evaluations were performed on a separate group of animals (four/sex) exposed to 0, 25, or 75 ppm for 6 months. A separate 90-day study using 20 rats/sex/treatment group was conducted at 0, 25, and 75 ppm, with an interim sacrifice of 8 rats/group at 30 days. There were no exposure-related changes in mortality, appearance and demeanor, body weight, clinical chemistry determinations, hematologic evaluations, urinalysis, or cytogenetic evaluation of bone marrow preparations.

Minimal hepatocellular fatty change in the midzonal region of the hepatic lobule was observed in both male and female rats in the 25 ppm and 75 ppm groups at the 6-month interim sacrifice (male: control, 0/5; 25 ppm, 1/5; 75 ppm, 4/5; female: control, 0/5; 25 ppm, 2/5; 75 ppm, 4/5). The fatty change was also observed at the 12-month sacrifice, but there was no indication of progression of severity (male: control, 0/5; 25 ppm, 3/5; 75 ppm, 5/5; female: control, 0/5; 25 ppm, 5/5; 75 ppm, 5/5). At the 18-month sacrifice the incidence of this change was no longer increased in male rats (control, 0/27; 25 ppm, 0/25; 75 ppm, 1/27). However, the change persisted in female rats (control, 0/16; 25 ppm, 6/29; 75 ppm, 7/20). The effect was statistically significant ($p<0.05$) only at the higher exposure. During the last 6 months of the study, after exposure had been discontinued, this effect was no longer discernible (male: control, 0/46; 25 ppm, 1/47; 75 ppm, 0/51; female: control, 0/49; 25 ppm, 0/46; 75 ppm, 1/48).

Although the incidences of several tumors and/or tumor types were found to be statistically increased or decreased compared with controls, none of these differences were judged to be attributable to 1,1-DCE. The tumor incidence data for both control and treated rats in this study were comparable to historical control data for the Sprague-Dawley rats (Spartan substrain) used by this laboratory for several studies of similar design and duration.

Although the minimal hepatocellular midzonal fatty change was reversible and did not result in altered organ weight, clinical chemistry changes diagnostic for liver damage, or any obvious decrement in liver function, the fatty change in liver is considered a minimal adverse effect. Accordingly, the NOAEL in male rats in this study is 75 ppm (the highest exposure tested). The NOAEL for female rats in this study is 25 ppm; the LOAEL is 75 ppm. A benchmark dose analysis was conducted. In female rats the BMC_{10} is 15.1 ppm and the $BMCL_{10}$ is 9.8 ppm, equivalent to 1.8 ppm adjusted for continuous exposure (9.8 ppm × 6/24 × 5/7).

__I.B.3. Uncertainty and Modifying Factors (Inhalation RfC)

UF = 30.

The critical effect is liver toxicity (fatty change) in rats with a $BMCL_{10HEC}$ of 6.9 mg/m^3. Although this minimal effect might not be considered adverse—as there is no evidence of a functional change in the liver in rats exposed at this level and glutathione levels are not reduced—it is used to derive the RfC, because limiting exposure to this level will protect the liver from more serious damage (fatty liver or necrosis) that could compromise liver function. The total UF is 30 and the modifying factor is 1. A UF of 3 is used for interspecies extrapolation because a dosimetric adjustment was used.

There is some suggestion that the effects in the kidney of male mice might occur at an exposure lower than the level that produced effects in the liver of rats. Thus, there is some uncertainty as to whether the most sensitive species has been used to derive the RfC. A UF of 10 is used for intraspecies variability because there were no applicable data to depart from the default value. Derivation of the RfD from the $BMDL_{10}$ for the minimum fatty change in the liver does not require an effect-level extrapolation. This conclusion is based on the minimal nature of the fatty change and its questionable biological significance because of the absence of any observable functional deficit in the liver. Although the animals were exposed for 18 months, rather than the full lifetime, there was no indication that the fatty change was progressing. In contrast, the evidence indicated the fatty change was decreasing in incidence with continued exposure. EPA, therefore, did not apply a subchronic-to-chronic extrapolation factor. A database UF is not applied because the database is considered complete.

A number of long-term bioassays in rodents by the oral or inhalation route show that liver toxicity is the critical effect. There is no chronic bioassay in a nonrodent mammal. However, there are 90-day bioassays in several species (rats, mice, dogs, guinea pigs, rabbits, and monkeys) that suggest similar exposure-response relationships across species. Therefore, the lack of a chronic bioassay in a nonrodent mammal is not considered a data gap. There are no focused studies on neurotoxicity, but there are no indications from chronic, reproductive, and developmental bioassays in rats and mice by oral or inhalation exposure that neurotoxicity is an important toxic endpoint. No long-term studies have evaluated immunotoxicity in laboratory animals by any route of exposure. The existing bioassays, however, provide no suggestion that immunotoxicity is a critical effect. EPA does not consider these data gaps compelling enough to require application of a database UF.

MF = 1.

__I.B.4. Additional Studies/Comments (Inhalation RfC)

Prendergast et al. (1967) evaluated the toxicity of 1,1-DCE in Long-Evans or Sprague-Dawley rats, Hartley guinea pigs, beagle dogs, New Zealand albino rabbits, and squirrel monkeys. The test animals (15 rats/group, 15 guinea pigs/group, 3 rabbits/group, 2 dogs/group, or 3 or 9 monkeys/group) were exposed continuously for 90 days to 1,1-DCE vapors at 189 ± 6.2, 101 ± 4.4, 61 ± 5.7, or 20 ± 2.1 mg/m^3. The concurrent controls included 304 rats, 314 guinea pigs, 48 rabbits, 34 dogs, and 57 monkeys. The age of the animals was not specified. The exposed animals were evaluated for visible signs of toxicity, mortality, and hematologic, biochemical, pathologic, and body weight changes. There was apparent exposure-related mortality in guinea pigs and monkeys. In guinea pigs the mortality was 2/314, 2/45, 3/15, 3/15, and 7/15 and in monkeys it was 1/57, 1/21, 0/9, 2/3, and 3/9 in the 0, 20, 61, 101, or 189 mg/m^3 exposure groups, respectively. The guinea pigs died between days 3 to 9 of exposure; the monkeys died on days 26, 39, 47, 60, and 64 of exposure. There were no visible signs of toxicity in any surviving animals.

At the highest exposure in monkeys, but not in guinea pigs, there was some histopathological evidence of liver damage (see below). In guinea pigs at the highest exposure, there was an increase in serum glutamic-pyruvic transaminase and liver alkaline transaminase (see below). Because visible signs of toxicity were not observed and only minor liver damage is apparent in this study, the mortality data in guinea pigs and monkeys are given no weight.

Varying degrees of growth depression were found in all exposures, but were significant in all species only at 189 mg/m^3. The test animals exhibited no significant hematologic alterations, and serum urea nitrogen levels were within control limits in all exposures in which determinations were made. Significant elevations of serum glutamic-pyruvic transaminase and liver alkaline phosphatase activities were found in rats (a threefold and 1.75-fold increase, respectively) and guinea pigs (sevenfold and 2.4-fold increase, respectively) exposed to 189 mg/m^3 (other species not tested) but not at 20 mg/m^3 (enzyme levels at intermediate exposures not tested). Histopathological examination of liver from dogs, monkeys, and rats revealed damage at 189 mg/m^3 (other species not examined). The effects observed included fatty metamorphosis, focal necrosis, hemosiderosis deposition, lymphocytic infiltration, bile duct proliferation, and fibrosis. The changes were most severe in dogs. Sections of kidney from all rats showed nuclear hypertrophy of the tubular epithelium. No detectable liver or kidney damage was observed in any species exposed to 101 mg/m^3 or less. The NOAEL in this study is 101 mg/m^3 (equivalent to 25 ppm); the LOAEL is 189 mg/m^3 (equivalent to 47 ppm).

Short et al. (1977) evaluated developmental toxicity of 1,1-DCE administered by inhalation to pregnant CD-1 rats (Charles River). Animals were exposed to 0 (58 animals), 15 ppm (18 animals), 57 ppm (20 animals), 300 ppm (18 animals), or 449 ppm (18 animals) for 22-23 hours/day on gestation days 6 to 16. Dams were sacrificed on gestation day 20. Maternal toxicity was exhibited as severe maternal weight loss (> 28 grams/dam) at 15 ppm and higher and by maternal mortality at 57 ppm and higher. There was a statistically significant increase in the mean number of fetuses per litter with hydrocephalus at 15 and 57 ppm, with malaligned sternebrae at 15 ppm, and with unossified sternebrae at 57 ppm. Because of the severe maternal toxicity at 15 ppm (60 mg/m^3) and higher, this study is not useful for evaluating developmental toxicity.

Short et al. (1977) evaluated developmental toxicity of 1,1-DCE administered by inhalation to pregnant CD-1 mice (Charles River). Animals were exposed to 0 (65 animals), 15 ppm (23 animals), 30 ppm (19 animals), 57 ppm (21 animals), 144 ppm (18 animals), or 300 ppm (15 animals) for 22–23 hrs/day on gestation days 6 to 16. Dams were sacrificed on gestation day 17. At 30 ppm and higher there was maternal toxicity, as shown by statistically significant decreases in maternal weight gain. At 144 and 300 ppm there was an increase in maternal mortality. At 30 ppm and higher there was severe fetal toxicity, with complete early resorption of the litters. At 15 ppm there was no evidence of maternal toxicity, no decrease in fetal body weight, and no decrease in the percentage of viable fetuses. At 15 ppm, there was an increase in the mean number of fetuses per litter with hydrocephalus, occluded nasal passages, micropthalmia, cleft palate, small liver, and hydronephrosis. None of these changes, however, were statistically significant when compared to controls. Also at 15 ppm there was a statistically significant increase in the mean number of fetuses with an unossified incus and with incompletely ossified sternebrae. This study provides evidence of fetal toxicity at 15 ppm, the only exposure without significant maternal toxicity. In this study the LOAEL for developmental toxicity is 15 ppm (60 mg/m^3), the lowest exposure tested.

Short et al. (1977) also evaluated developmental neurotoxicity of 1,1-DCE administered by inhalation to CD-1 rats (Charles River). Pregnant rats were exposed to 0 (24 animals), 56 ppm (20 animals), or 283 ppm (19 animals) for 22–23 hrs/day on gestation days 8 to 20. Maternal toxicity was observed at both exposures, as shown by weight loss of 7 g per dam at 56 ppm and 15 grams per dam at 283 ppm. There was complete resorption of three litters at 283 ppm. There was a statistically significant decrease in average pup weight as compared to control at both exposures on post-natal day 1. The difference in pup weight between control and exposed groups decreased with time and disappeared by postnatal day 21. There was no evidence of developmental neurotoxicity at either exposure in pups tested at various times from postnatal day 1 to day 21 in a battery of behavioral tasks, including surface righting, pivoting, auditory startle, bar holding, righting in air, visual placing, swimming ability, physical maturation, and activity. This study shows evidence of maternal and fetal toxicity at both exposures but no evidence of developmental neurotoxicity at either exposure. Accordingly, the NOAEL for developmental neurotoxicity in this study is 283 ppm (1124 mg/m^3), the highest exposure tested.

Murray et al. (1979) evaluated developmental toxicity of 1,1-DCE administered by inhalation to pregnant Sprague-Dawley rats (body weight 250 g). Animals were exposed to 0 (20 or 47 animals), 20 ppm (44 animals), 80 ppm (30 animals), or 160 ppm (30 animals) for 7 hrs/day on gestation days 6–15. At 20 ppm there was no maternal toxicity and no effect on embryonal or fetal development. At 80 and 160 ppm, there was toxicity to the dams (statistically significant depression in weight gain at gestation day 6–9, more severe at 160 ppm). At 80 and 160 ppm, there were also statistically significant increased incidences of wavy ribs and delayed ossification of the skull, which are regarded as embryotoxic effects. Both effects were more severe at 160 ppm. No teratogenic effects were seen at any exposure. The NOAEL for developmental toxicity in this study is 20 ppm; the LOAEL is 80 ppm. Under the Guidelines for Developmental Toxicity (U.S. EPA, 1994), these values are not adjusted to continuous exposure.

Murray et al. (1979) evaluated the developmental toxicity of 1,1-DCE administered by inhalation to New Zealand white rabbits (body weight 3.4–4.7 kg). Animals were exposed to 0 (16 animals), 80 ppm (22 animals), or 160 ppm (18 animals) for 7 hrs/day on gestation days 6–18. At 80 ppm there was no maternal toxicity and no effect on embryonal or fetal development. Toxicity to both the dams and their developing embryos was observed at 160 ppm. There was a marked increase in the incidence of resorptions per litter (0.3 ± 0.6 vs. 2.7 ± 3.9). A significant change occurred in the incidence of several minor skeletal variations in their offspring, including an increase in the occurrence of 13 pairs of ribs and a increased incidence of delayed ossification of the fifth sternebra (data not reported). No teratogenic effects were seen at any exposure. The NOAEL for developmental toxicity in this study is 80 ppm; the LOAEL is 160 ppm. Under the Guidelines for Developmental Toxicity (U.S. EPA, 1991), these values are not adjusted to continuous exposure.

See also studies showing liver toxicity and the reproductive and developmental studies summarized in the RfD section.

For more detail on Susceptible Populations, exit to the toxicological review, Section 4.7 (PDF).

__I.B.5. Confidence in the Inhalation RfC

Study — High
Database — Medium
RfC — Medium

The overall confidence in this RfC assessment is medium. The principal study (Quast, 1986) was a well-conducted inhalation bioassay with adequate numbers of animals and appropriate evaluation of a wide variety of endpoints. The result is supported by several other 90-day inhalation studies in a variety of species (Prendergast et al. 1967). These inhalation studies are supported by an additional bioassay in rats and a 90-day study in dogs, both by the oral route of exposure showing NOAELs (see the summary of these studies in the RfD section). There is no evidence from the inhalation bioassays that the respiratory tract is a target tissue of low-dose exposure. Several studies by the inhalation route of exposure show that developmental toxicity is not a critical effect. A three-generation reproductive study by the oral route of exposure showed no significant reproductive effects, and several bioassays showed no developmental toxicity. However, one developmental study by the oral route of exposure shows variations in cardiac morphology that appear to have little or no physiological consequence. There are no focused studies on neurotoxicity, but no indication from chronic, reproductive, and developmental bioassays in rats and mice by oral or inhalation exposure that neurotoxicity is an important toxic endpoint. No long-term studies have evaluated immunotoxicity in laboratory animals by any route of exposure. The existing bioassays, however, provide no suggestion that immunotoxicity is a critical effect. Accordingly, the database is given medium confidence, but no additional UF is considered necessary.

For more detail on Characterization of Hazard and Dose Response, exit to the toxicological review, Section 6 (PDF).

__I.B.6. EPA Documentation and Review of the Inhalation RfC

Source Document — Toxicological Review of 1,1-Dichloroethylene (2002)

This assessment was peer reviewed by external scientists. Their comments have been evaluated carefully and incorporated in finalization of this IRIS Summary. A record of these comments is included as an appendix to the Toxicological Review of 1,1-Dichloroethylene. ***To review this appendix, exit to the toxicological review, Appendix A, Summary of and Response to External Peer Review Comments (PDF).***

Other EPA Documentation — None.

Agency Consensus Date — 06/07/2002

A comprehensive review of toxicological studies published through May 2005 was conducted. No new health effects data were identified that would be directly useful in the revision of the existing RfC for 1,1-Dichloroethylene (1,1-DCE) and a change in the RfC is not warranted at this time. For more information, IRIS users may contact the IRIS Hotline at hotline.iris@epa.gov or 202-566-1676.

I.B.7. EPA Contacts (Inhalation RfC)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX), or hotline.iris@epa.gov (email address).

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II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — 1,1-Dichloroethylene (1,1-DCE)
CASRN — 75-35-4
Last Revised — 08/13/2002

Section II provides information on three aspects of the carcinogenic assessment for the substance in question: the weight-of-evidence judgment of the likelihood that the substance is a human carcinogen and quantitative estimates of risk from oral exposure and from inhalation exposure. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per (mg/kg)/day. The unit risk is the quantitative estimate in terms of either risk per µg/L drinking water or risk per µg/cu.m air breathed. The third form in which risk is presented is a concentration of the chemical in drinking water or air associated with cancer risks of 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. The rationale and methods used to develop the carcinogenicity information in IRIS are described in The Risk Assessment Guidelines of 1986 (EPA/600/8-87/045) and in the IRIS Background Document. IRIS summaries developed since the publication of EPA's more recent Proposed Guidelines for Carcinogen Risk Assessment also utilize those Guidelines where indicated (Federal Register 61(79):17960-18011, April 23, 1996). Users are referred to Section I of this IRIS file for information on long-term toxic effects other than carcinogenicity.

This IRIS Summary replaces the summary dated 03/31/1987. The assessment of carcinogenicity by the inhalation route of exposure under the draft revised guidelines for carcinogen risk assessment (U.S. EPA, 1999) differs from the previous EPA evaluation (U.S. EPA, 1985a, b). EPA's previous evaluation considered the incidence of kidney adenocarcinomas (Maltoni et al., 1985) as providing sufficient evidence of carcinogenicity to justify deriving an inhalation unit risk for quantifying the potential human cancer risk. As noted in Sections 4.4.3 and 4.6 of the Toxicological Review of 1,1-Dichloroethylene, the new data suggesting that the kidney adenocarcinomas could be a sex- and species-specific response reduce the weight-of-evidence for carcinogenicity by the inhalation route of exposure. Accordingly, the present evaluation does not derive an inhalation unit risk. This conclusion is consistent with the evaluation by the International Agency for Research on Cancer (IARC) (IARC, 1999).

In addition, this assessment of carcinogenicity by the oral route of exposure under the draft revised guidelines for carcinogen risk assessment (U.S. EPA, 1999) differs from the previous EPA evaluation (U.S. EPA, 1985a, b). The previous EPA evaluation derived an oral slope factor from the highest of four slope factors calculated from two studies (NTP, 1982; Quast et al., 1983) that did not show statistically significant increases in tumor incidence attributable to oral exposure. The highest slope factor was based on the adrenal pheochromocytomas in male rats (NTP, 1982). Under the 1999 draft revised guidelines for carcinogen risk assessment, EPA emphasizes the importance of using data that show a statistically significant increase in tumor incidence for calculating a slope factor. As there is no statistically or biologically significant increase in tumor incidence at any site in the relevant oral bioassays, the present evaluation characterizes the weight-of-evidence as *inadequate* and accordingly does not derive an oral slope factor. This conclusion is consistent with the evaluation by IARC (1999).

_II.A. Evidence for Human Carcinogenicity

__II.A.1. Weight-of-Evidence Characterization

Under the 1986 cancer guidelines (U.S. EPA, 1986), 1,1-DCE is assigned to Group C, possible human carcinogen.

Under the draft revised guidelines for carcinogen risk assessment (U.S. EPA, 1999), EPA concludes 1,1-DCE exhibits *suggestive evidence* of carcinogenicity but not sufficient evidence to assess human carcinogenic potential following inhalation exposure in studies in rodents. Male mice developed kidney tumors at one exposure in a lifetime bioassay, a finding tempered by the absence of similar results in female mice or male or female rats and by the enzymatic differences (i.e., CYP2E1) between male mice and female mice, male and female rats, and human kidney cells. Limited evidence of genotoxicity has been reported in bacterial systems with metabolic activation. The data for 1,1-DCE are *inadequate* for an assessment of human carcinogenic potential by the oral route, based on the absence of statistically or biologically significant tumors in limited bioassays in rats and mice balanced against the suggestive evidence in male mice in a single bioassay by inhalation and the limited evidence of genotoxicity. The human epidemiological results on the carcinogenicity of 1,1-DCE are too limited to draw useful conclusions. EPA concludes that the results of kidney tumors in one sex and one exposure in a single species of rodents are too limited to support an exposure-response assessment.

Bioassays for cancer by the oral route of exposure have been conducted in rats (Maltoni et al., 1985; NTP, 1982; Ponomarkov and Tomatis, 1980; Quast et al., 1983) mice (NTP, 1982), and trout (Hendricks et al., 1995). Some of these bioassays were conducted at an exposure below the maximum tolerated dose. The bioassay conducted by Maltoni et al. (1985) exposed the animals for only 1 year. The bioassay conducted in rats by Quast et al. (1983) and the bioassay conducted in mice by NTP (1982) were well conducted and both showed some toxicity in the liver at the highest exposure. Neither of these bioassays provides any significant evidence that 1,1-DCE is a carcinogen by the oral route of exposure. The genotoxicity studies are incomplete, but most studies in mammalian cells indicate a lack of genotoxicity.

Bioassays for cancer by the inhalation route of exposure have been conducted in rats (Lee et al., 1977, 1978; Viola and Caputo, 1977; Hong et al., 1981; Maltoni et al., 1985; Quast et al., 1986; Cotti et al., 1988), mice (Lee et al., 1977, 1978; Hong et al., 1981; Maltoni et al., 1985), and hamsters (Maltoni et al., 1985). None of these bioassays was conducted by a protocol that meets current standards. The major defects in most of these bioassays include exposure of the animals for 1 year and exposure at less than the maximum tolerated dose. The only bioassay that showed some evidence of carcinogenicity was the study in Swiss-Webster mice (Maltoni et al., 1985). This study was conducted at or near the maximum tolerated dose, as animals exposed at 50 ppm died after a few exposures. Although the animals were exposed for only 1 year and then observed until natural death, this study showed an increased incidence of kidney adenocarcinomas in male mice at 25 ppm but not at 10 ppm. The incidence of mammary carcinomas in female mice and pulmonary adenomas in male and female mice did not increase with increased exposure. The responses were actually lower at 25 ppm than at 10 ppm, but survival and other toxicities were comparable.

There is evidence that the induction of kidney adenocarcinomas is a sex- and species-specific response related to the expression of CYP2E1 in the kidney of male mice (Speerschneider and Dekant, 1995; Amet et al., 1997; Cummings et al., 2000). The data presented by these researchers, however, are not sufficient to justify a conclusion that the kidney tumors in male mice have no relevance for a human health risk assessment. This conclusion is made with the knowledge that compounds similar in structure to 1,1-DCE (e.g., tetrachloroethylene, trichloroethylene, and 1,2-dichloroethylene) produce varying degrees of kidney tumors in animal bioassays.

The genotoxicity studies are incomplete, but most studies in mammalian cells indicate a lack of genotoxicity. Accordingly, EPA concludes that the data on the increased incidence of kidney adenocarcinomas in male mice (Maltoni et al., 1985) provide *suggestive evidence* of carcinogenicity by the inhalation route of exposure. EPA also concludes, considering the evidence of a potential sex- and species-specific response, that the results of this bioassay showing an increase in tumors in one sex and one exposure in a single species of rodents are too limited to support an exposure-response assessment.

1,1-DCE causes gene mutations in microorganisms in the presence of an exogenous activation system. Although most tests with mammalian cells show no evidence of genetic toxicity, the test battery is incomplete because it lacks an in vivo test for chromosomal damage in the mouse lymphoma system.

There are a number of uncertainties in the assessment of the carcinogenicity of 1,1-DCE. As noted above, many of the bioassays by the inhalation route of exposure were not conducted at the maximum tolerated dose or for the full lifetime of the animals. EPA has acknowledged this uncertainty in the weight-of-evidence classification. In addition, our knowledge of the metabolic pathways for 1,1-DCE in the human is incomplete. Although it is likely that the initial oxidation of 1,1-DCE in humans occurs via CYP2E1, there could be other CYP isoforms that could activate 1,1-DCE. Thus, there is some potential for a species-specific carcinogenic response in humans similar to the apparent sex- and species-specific response observed by Maltoni et al. (1985) in the kidney of male mice.

For more detail on Characterization of Hazard and Dose Response, exit to the toxicological review, Section 6 (PDF).

For more detail on Susceptible Populations, exit to the toxicological review, Section 4.7 (PDF).

__II.A.2. Human Carcinogenicity Data

Ott et al. (1976) investigated the health records of 138 employees occupationally exposed to 1,1-DCE in processes not involving vinyl chloride. The individuals included in the study had worked in experimental or pilot plant polymerization operations, in a monomer production process as tankcar loaders, or in a production plant that manufactured a monofilament fiber. Time-weighted-average concentrations (8 hours) of 1,1-DCE in the workplace were estimated from job descriptions and the results of industrial hygiene sampling. The subjects were grouped into three exposure categories: less than 10 ppm, 10–;24 ppm, and greater than 25 ppm. The researchers estimated career exposure by taking into account average duration of employment. Results of the most recent health inventory for individuals in the cohort were compared with findings of matched controls. Analysis of mortalities among the cohort indicated no statistically significant findings. Overall, there were no significant differences between the exposed cohort and the controls in hematology and clinical chemistry parameters. Based on power considerations, this study is inadequate for assessing cancer risk in humans.

__II.A.3. Animal Carcinogenicity Data

Oral

Rats. Ponomarkov and Tomatis (1980) treated 24 female BD IV rats by gavage with 1,1-DCE dissolved in olive oil (150 mg/kg body weight) on the 17th day of gestation. Their offspring (81 males and 80 females) were treated weekly with 1,1-DCE at 50 mg/kg body weight by gavage from the time of weaning for 120 weeks or until the animal was moribund. A control group of offspring (49 males and 47 females) received only olive oil. Liver and meningeal tumors were more frequently observed in treated than in untreated animals, but the difference was not statistically significant. The total number of tumor-bearing animals was not statistically different between treated and untreated animals.

NTP (1982) conducted chronic toxicity and carcinogenicity studies of 1,1-DCE for 104 weeks in male and female F344 rats (200 of each sex, 9 weeks old) by gavage in corn oil at 0, 1, or 5 mg/kg-day. No significant differences were observed in survival, clinical signs, or body weight as compared with controls for any group, suggesting that the maximum tolerated dose was not achieved. All of the increased tumor incidences that were statistically significant by the Fisher exact test or by the Cochran-Armitage linear trend test (adrenal pheochromocytoma, pancreatic islet cell adenoma or carcinoma, and subcutaneous fibroma in males and pituitary adenoma in females) were not significant when life-table analyses were used. This difference occurs because life table analyses adjust for intercurrent mortality, and thus minimize the impact of animals dying before the onset of late-appearing tumor. This adjustment was particularly critical for the analyses of tumor incidences in male rats, because 12 controls and 10 low-dose animals were accidentally killed during week 82 of the study. Accordingly, NTP concluded that no increased incidence of tumors was found at any site in these bioassays. Under the conditions of this bioassay, 1,1-DCE administered by gavage was not carcinogenic for F344 rats.

Quast et al. (1983) conducted a 2-year chronic toxicity and carcinogenicity study of 1,1-DCE in Sprague-Dawley rats (6–7 weeks old). There were 80 of each sex rats in the control group and 48 rats of each sex in each exposed group. The 1,1-DCE was incorporated in the drinking water of the rats at nominal concentrations of 0, 50, 100, or 200 ppm. The time-weighted-average exposure over the 2-year period was 7, 10, or 20 mg/kg-day for males and 9, 14, or 30 mg/kg-day for females. No significant differences were found among the groups in appearance and demeanor, mortality, body weight, food consumption, water consumption, hematology, urinalysis, clinical chemistry determinations, organ weights, or organ-to-body-weight ratios. The only treatment-related effect observed in rats was a minimal amount of midzonal fatty change and hepatocellular swelling. No exposure-related neoplastic changes occurred at any exposure.

Maltoni et al. (1985) conducted a carcinogenicity and toxicity study of 1,1-DCE in Sprague-Dawley rats. Animals (9 or 10 weeks old) were exposed by gavage in olive oil to 0, 0.5, 5, 10, or 20 mg/kg, 4–5 days/wk for 52 weeks. There were two control groups, one with 150 animals (75 of each sex) and the other with 200 animals (100 of each sex). The exposed groups had 100 animals (50 of each sex). Following the 52-week exposure, animals were observed until spontaneous death (total duration 147 weeks). Body weight was measured every 2 weeks during the 52 week exposure and every 8 weeks thereafter. Full necropsy and histopathological examination were performed. No biologically significant changes were observed in mortality or body weight. There were no biologically significant noncancer or cancer effects in any organ.

Mice. NTP (1982) conducted 104 weeks of chronic toxicity and carcinogenicity studies on 1,1-DCE in male and female $B6C3F_1$ mice (200 of each sex, 9 weeks old) by gavage in corn oil at 0, 2, or 10 mg/kg. No significant differences in survival, clinical signs, or body weight were in any group, suggesting that the maximum tolerated dose was not achieved. The only observed significant increase ($p<0.05$) in tumor incidence occurred in low-dose females for lymphoma (2/48, 9/49, 6/50) and for lymphoma or leukemia (7/48, 15/49, 7/50). These increases were not considered to be related to 1,1-DCE administration because similar effects were not found in the high-dose females or in males. Under the conditions of this bioassay, 1,1-DCE administered by gavage was not carcinogenic for $B6C3F_1$ mice.

Trout. Hendricks et al. (1995) conducted an 18-month carcinogenicity study of 1,1-DCE in rainbow trout (8 weeks old) at 4 mg/kg-day. Tissues examined for neoplasms included liver, kidney, spleen, gill, gonads, thymus, thyroid, heart, stomach, pyloric ceca, duodenum, rectum, pancreas, and swimbladder. 1,1-DCE produced no neoplasms and no increase in liver weight. There was no evidence of any other chronic toxic effects.

Inhalation

Rats. Lee et al. (1977, 1978) exposed 2-month-old Charles River CD rats (36 males and 35 females) to 55 ppm 1,1-DCE for 6 hrs/day, 5 days/wk, for 12 months. No significant changes were observed in survival, body weight, hematology, clinical blood chemistry, pulmonary macrophage count, cytogenetic analysis of bone marrow, x-ray examination of extremities, collagen contents in liver and lung, serum aminolevulinic acid (ALA) synthetase, urinary ALA level, and serum alpha-fetoprotein. A mild to markedly severe focal, disseminated vacuolization was observed in livers of most of the rats. No hemangiosarcomas were found in the liver or lung. The incidence of hemangiosarcomas in mesenteric lymph node or subcutaneous tissue was 2/36 in males and 0/35 in females.

Viola and Caputo (1977) exposed 2-month-old Sprague-Dawley rats (30 males and 30 females per group) to 0, 75 ppm, or 100 ppm 1,1-DCE for 22–24 months (hours of daily exposure not reported). The incidence of tumors observed at necropsy (males and females combined) was 15/60; 10/36 and 20/60 at 0, 75 ppm, and 100 ppm, respectively. The tumors observed were classified as subcutaneous fibromas or abdominal lymphomas. The histopathological results from this study have not been published. No other data are reported for this study.

Viola and Caputo (1977) also exposed 2-month-old albino Wistar rats (37 males and 37 females) to 1,1-DCE for 4 hrs/day, 5 days/wk, for 12 months. The exposure was at 200 ppm for the first 6 months and at 100 ppm for the rest of the study. A control group of 60 animals received air only. The incidence of tumors (described as reticulum cell sarcomas of a nonsincytial type, primarily in the abdominal cavity) was 15/60 and 17/74 in control and exposed groups, respectively. No other data are reported from this study.

Hong et al. (1981) evaluated mortality and tumor incidence in rats exposed to 1,1-DCE. Groups of 2-month-old CD rats of both sexes were exposed to 0 or 55 ppm 1,1-DCE 6 hrs/day, 4 days/wk for 1 month (four of each sex), 3 months (four of each sex), 6 months (four of each sex), or 10 months (16 of each sex). Following exposure, all animals were observed for an additional 12 months. In rats exposed for 10 months, there was an increase in mortality following the 12-month observation period (67% in exposed, 41% in controls). There was no significant increase in tumors at any site for any exposure period.

Maltoni et al. (1985) conducted a carcinogenicity and toxicity study of 1,1-DCE in Sprague-Dawley rats. Animals (16 weeks old) were exposed by inhalation to 0, 10, 25, 50, 100, or 150 ppm for 4 hrs/day, 4–5 days/wk for 52 weeks. The control group had 200 animals (100 of each sex); the 10, 25, 50, and 100 ppm groups had 60 animals (30 of each sex), and the 150 ppm group had 120 animals (60 of each sex). Following the 52-week exposure, animals were observed until spontaneous death (total duration 137 weeks). Body weight was measured every 2 weeks during the 52-week exposure and every 8 weeks thereafter. Full necropsy and histopathological examination were performed. No biologically significant changes were seen in mortality or body weight. There were no biologically significant noncancer effects in any organ in either sex and no increase in tumors in males at any site. There was a statistically significant increase ($p<0.05$) in each treatment group as compared with controls in the number of females with mammary fibromas and fibroadenomas. The incidence was 44/56 (78.6%), 24/24 (100%), 20/20 (100%), 21/22 (95.4%), 21/23 (91.3%), and 38/43 (88.4%) in the control, 10, 25, 50, 100, and 150 ppm groups, respectively. The latency time and the number of tumors per tumor-bearing animal were similar among all groups. The incidence of mammary carcinoma in exposed groups was consistently less than that of controls. The incidence was 16/56 (28.6%), 5/24 (20.8%), 4/20 (20%), 1/21 (4.5%), 3/21 (13.0%), and 9/38 (20.9%) in the control, 10, 25, 50, 100, and 150 ppm groups, respectively.

Quast et al. (1986) and Rampy et al. (1977) reported results from studies that exposed male and female Sprague-Dawley rats (Spartan substrain, 86 animals/group) to 1,1-DCE by inhalation 6 hrs/day, 5 days/wk, for up to 18 months. Interim sacrifices occurred at 1, 6, and 12 months. Rats were exposed to 1,1-DCE concentrations of 10 ppm and 40 ppm for the first 5 weeks of the study. Based on the absence of observable treatment-related effects among rats sacrificed after 1 month of exposure, the concentrations were increased to 25 and 75 ppm. Exposures were continued at these concentrations through the 18th month of the study. The surviving animals were then held without exposure to 1,1-DCE until 24 months. Cytogenetic evaluations were performed on a separate group of animals (four per sex) exposed to 0, 25, or 75 ppm for 6 months. There were no exposure-related changes in mortality, appearance and demeanor, body weight, clinical chemistry determinations, hematologic evaluations, urinalysis, or cytogenetic evaluation of bone marrow preparations. Although the incidences of several tumors and/or tumor types were found to be statistically increased or decreased as compared with controls, none of these differences were judged to be attributable to 1,1-DCE. The tumor incidence data for both control and treated rats in this study were comparable to historical control data for the Sprague-Dawley rats (Spartan substrain) used by this laboratory for several studies of similar design and duration.

Cotti et al. (1988) exposed Sprague-Dawley rats to 1,1-DCE at 0 or 100 ppm for 4–7 hrs/day, 5 days/wk. The exposures were to 13-week-old females for 104 weeks (60 control animals and 54 exposed animals) and to 12-day embryos for 15 or 104 weeks (158 males and 149 females as controls, 60 males and 60 females exposed for 15 weeks, and 62 males and 61 females exposed for 104 weeks). Animals were observed until spontaneous death. In males and females exposed for 104 weeks and in male offspring exposed for 15 weeks, a slight decrease in body weight (data not reported) was observed. An increased percentage of rats bearing malignant tumors (30.9% vs. 17.3 % in controls) and an increased number of malignant tumors per 100 animals (34.1% vs. 17.9% in controls) were observed in male and female offspring exposed for 104 weeks (statistical analysis not presented). An increase in leukemia in offspring, which appeared to be related to length of exposure (4.2% for controls, and 8.3% and 11.4% for exposure of 15 and 104 weeks, respectively), was also observed. Tumors at other sites (total benign and malignant tumors, total benign and malignant mammary tumors, malignant mammary tumors, and pheochromocytomas) showed no change or a decreased incidence. Data from this study are also reported in Maltoni et al. (1985).

Mice. Lee et al. (1977, 1978) exposed 2-month-old CD-1 mice (18 males and 18 females) to 0 or 55 ppm 1,1-DCE for 6 hrs/day, 5 days/wk, for up to 12 months. No deaths occurred in the control or exposed groups. Weight gain was comparable between groups. There was no change in hematology, clinical blood chemistry, cytogenetic analysis of bone marrow, x-ray examination of extremities, or serum alpha-fetoprotein. The livers showed no increase in mitotic figures using ^{14}C-thymidine incorporation. The incidence of bronchioalveolar adenoma (males and females combined) for 1–3 months exposure, 4–6 months exposure, 7–9 months exposure, and 10–12 months exposure was 0/24, 1/8, 2/10, and 3/28, respectively. The incidence of hemangiosarcomas in liver (males and females combined) for 6 months exposure, 7–9 months exposure, and 10–12 months exposure was 0/16, 1/10, and 2/28, respectively. No hemangiosarcomas were found in other tissues.

Hong et al. (1981) evaluated mortality and tumor incidence rates in mice exposed to 1,1-DCE. Groups of 2-month-old albino CD-1 mice of both sexes were exposed to 0 or 55 ppm for 6 hrs/day, 4 days/wk, for 1 month (8 of each sex), 3 months (8 of each sex), or 6 months (12 of each sex). Following exposure, all animals were observed for an additional 12 months. In mice exposed for 6 months, there was a slight increase in mortality following the 12-month observation period (46% in exposed, 39% in controls). There was no significant increase in tumors at any site for any exposure period.

Maltoni et al. (1985) conducted a carcinogenicity and toxicity study of 1,1-DCE in Swiss mice. Animals (9 or 16 weeks old) were exposed by inhalation to 0, 10, or 25 ppm. Animals were exposed for 4 hrs/day, 4–5 days/wk, for 52 weeks. There were two control groups, one with 180 animals (90 of each sex) and the other with 200 animals (100 of each sex). The 10-ppm group had 60 animals (30 of each sex). Two groups were exposed to 25 ppm: one with 60 animals (30 of each sex) and the other with

240 animals (120 of each sex). Following the 52-week exposure, animals were observed until spontaneous death (total duration 126 weeks). Body weight was measured every 2 weeks during the 52-week exposure and every 8 weeks thereafter. Full necropsy and histopathological examination were performed.

No biologically significant changes occurred in body weight. The exposed animals had a somewhat higher survival than controls. There was a statistically significant increase (p<0.01) as compared with controls in kidney adenocarcinomas in male mice at 25 ppm but not in male mice at 10 ppm or in female mice at either exposure. The incidence was 0/126 (0%), 0/25 (0%), and 28/119 (23.5%) in male mice in the combined controls, 10 ppm, and combined 25 ppm groups, respectively.

There was a statistically significant increase (p<0.01) as compared with controls in mammary carcinomas in female mice at both exposures, but there was no clear exposure-response relationship. The incidence was 3/185 (1.6%), 6/30 (20%), and 16/148 (11%) in females in the combined controls, 10 ppm, and combined 25 ppm groups, respectively. There was also a statistically significant increase (p < 0.01) compared with control in pulmonary adenomas in both exposed groups, but there was no clear exposure-response relationship. The incidence was 12/331 (3.6%), 14/58 (24.1%), and 41/288 (14.2%) in male and female mice combined in the combined controls, 10 ppm, and combined 25 ppm groups, respectively. There were no pulmonary carcinomas in any mice. The incidence data are reported as the number of tumor-bearing animals as compared with the number of animals alive when the first tumor was observed in that organ (kidney adenocarcinoma, 55 weeks; mammary tumor, 27 weeks; pulmonary adenoma, 36 weeks)

Hamsters. Maltoni et al. (1985) conducted a carcinogenicity and toxicity study of 1,1-DCE in Chinese hamsters. Animals (28 weeks old) were exposed by inhalation to 0 or 25 ppm. Animals were exposed for 4 hrs/day, 4-5 days/wk, for 52 weeks. The control group had 35 animals (18 male and 17 female); the 25 ppm group had 60 animals (30 of each sex). Following the 52-week exposure, animals were observed until spontaneous death (total duration 157 weeks). Body weight was measured every 2 weeks during the 52-week exposure and every 8 weeks thereafter. Full necropsy and histopathological examination were performed. There were no biologically significant changes in mortality or body weight. No biologically significant noncancer or tumor effects were seen in any organ.

Dermal. Van Duuren et al. (1979) evaluated the carcinogenicity of 1,1-DCE in male and female noninbred Ha:ICR Swiss mice. Carcinogenicity was assessed in three types of tests: a dermal initiation-promotion assay, a repeated dermal application assay, and a subcutaneous injection assay. Vehicle, no-treatment, and positive control groups were included in the tests. In the initiation-promotion assay, 1,1-DCE was tested as a tumor-initiating agent with phorbol myristate acetate as the promoter. Thirty female mice were treated with 121 mg 1,1-DCE. A significant increase (p<0.005) was observed in skin papillomas (nine in eight mice). In the repeated dermal application assay, exposures of 40 and 121 mg/mouse were used. 1,1-DCE was applied to the back of the shaved animals (30 females/dose). No sarcomas were observed at the treatment site. Although 19 mice in the high-dose group and 12 in the low-dose group had lung tumors and 2 mice in the high-dose group had stomach tumors, the tumor incidence at both sites was not significantly different from that of controls (30 lung tumors and 5 stomach tumors). In the subcutaneous injection assay, the test animals were given weekly injections of 2 mg of 1,1-DCE. After 548 days on test, none of the injected animals developed sarcomas at the injection site. 1,1-DCE showed initiating activity in the two-stage carcinogenesis experiments but was inactive as a whole-mouse dermal carcinogen and after subcutaneous injection.

__II.A.4. Supporting Data for Carcinogenicity

Reitz et al. (1980) investigated the ability of 1,1-DCE to cause DNA alkylation, DNA repair, and DNA replication in liver and kidney of rats and mice. Male Sprague-Dawley rats (body weight 200–250 g) and male CD-1 mice (body weight 18–20 g) were exposed by inhalation for 6 hours. There was only a minimal increase in DNA alkylation in both rats and mice at 50 ppm. Similarly, DNA repair in kidneys of mice was only minimally increased at 50 ppm. However, tissue damage (kidney nephrosis at 50 ppm, minimal effect at 10 ppm), an increase in DNA replication (sevenfold increase in ^{3}H-thymidine incorporation at 10 ppm, 25-fold increase at 50 ppm), and an increase in mitotic figures occurred. There was no observed histopathological damage or increased DNA replication in the liver of mice at 10 or 50 ppm. In rats there was a small increase in DNA replication (twofold increase in ^{3}H-thymidine incorporation) in the kidney but no increase in liver at 10 ppm.

1,1-DCE induced mutations in *Salmonella typhimurium* and *Escherichia coli* in the presence of an exogenous metabolic system. In *Saccharomyces cerevisiae*, 1,1-DCE induced reverse mutation and mitotic gene conversion in vitro and in a host-mediated assay in mice. In a single study in *Saccharomyces cerevisiae*, it induced aneuploidy in the presence and absence of metabolic activation. In vitro, gene mutations were increased in mouse lymphoma cells but not in Chinese hamster lung cells with or without an exogenous metabolic system. In a single study, 1,1-DCE induced sister chromatid exchanges in Chinese hamster lung cells in the presence of an exogenous metabolic system but not in its absence. In single studies in vivo, 1,1-DCE did not induce micronuclei or chromosomal aberrations in bone marrow or in fetal erythrocytes of mice, nor dominant lethal mutations in mice or rats.

1,1-DCE causes gene mutations in microorganisms in the presence of an exogenous activation system. Although most tests with mammalian cells show no evidence of genetic toxicity, the test battery is incomplete because it lacks an in vivo assessment of chromosomal damage in the mouse lymphoma assay, a test that EPA considers to be an important component of a genotoxicity battery.

Speerschneider and Dekant (1995) investigated the metabolic basis for the species- and sex-specific nephrotoxicity and tumorigenicity of 1,1-DCE. In kidney microsomes from male mice, the rate of oxidation of 1,1-DCE depended on the hormonal status of the animals. Oxidation of 1,1-DCE was decreased by castration and restored when the castrate was supplemented with exogenous testosterone. In kidney microsomes from naive female mice, the rate of oxidation of 1,1-DCE was significantly lower than in males, but it could be increased by administration of exogenous testosterone. Using an antibody to rat liver CYP2E1, the researchers showed expression of a cross-eacting protein in male mouse kidney microsomes that was regulated by testosterone and correlated with the ability to oxidize 1,1-DCE and other substrates for CYP2E1 (e.g., p-nitrophenol and chlorozoxazone).

The researchers also showed that different strains of mice express different levels of CYP2E1, and the strains most sensitive to the effects of 1,1-DCE express greater levels of CYP2E1. Nephrotoxicity in Swiss-Webster mice after inhalation of 1,1-DCE was observed in males and in females treated with exogenous testosterone, but not in naive females. In kidney microsomes obtained from both sexes of rats and in six samples of human kidney from male donors, no p-nitrophenol oxidase activity was detected. Other research groups have also reported the absence of detectable CYP2E1 in human kidney tissue (Amet et al., 1997; Cummings et al., 2000).

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_II.B. Quantitative Estimate of Carcinogenic Risk from Oral Exposure

Not applicable. 1,1-DCE shows equivocal evidence of carcinogenicity by the oral route of exposure.

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_II.C. Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure

Not applicable. 1,1-DCE shows suggestive evidence of human carcinogenicity by the inhalation route of exposure. The weight-of-evidence, however, is not sufficient to justify deriving an inhalation unit risk.

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_II.D. EPA Documentation, Review, and Contacts (Carcinogenicity Assessment)

__II.D.1. EPA Documentation

Source Document — Toxicological Review of 1,1-Dichloroethylene (2002)

This assessment was peer reviewed by external scientists. Their comments have been evaluated carefully and incorporated in finalization of this IRIS Summary. A record of these comments is included as an appendix to Toxicological Review of 1,1-Dichloroethylene. ***To review this appendix, exit to the toxicological review, Appendix A, Summary of and Response to External Peer Review Comments (PDF).***

Other EPA Documentation — This assessment replaces previous assessments (U.S. EPA, 1985a,b).

__II.D.2. EPA Review (Carcinogenicity Assessment)

Agency Consensus Date — 06/07/2002

A comprehensive review of toxicological studies published through May 2005 was conducted. No new health effects data were identified that would be directly useful in the revision of the existing carcinogenicity assessment for 1,1-Dichloroethylene (1,1-DCE) and a change in the assessment is not warranted at this time. For more information, IRIS users may contact the IRIS Hotline at hotline.iris@epa.gov or 202-566-1676.

__II.D.3. EPA Contacts (Carcinogenicity Assessment)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX), or hotline.iris@epa.gov (email address).

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_III. [reserved]
_IV. [reserved]
_V. [reserved]

_VI. Bibliography

Substance Name — 1,1-Dichloroethylene (DCE)
CASRN — 75-35-4
Last Revised — 08/13/2002

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_VI.B. Inhalation RfC References

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_VII. Revision History

Substance Name — 1,1-Dichoroethene (DCE)
CASRN — 75-35-4
Primary Synonym — Vinylidene Chloride

Date	Section	Description
03/31/1987	II.	Carcinogenicity Section added
03/01/1988	I.A.1.	Dose conversion clarified
03/01/1988	I.A.7.	Contact changed
03/01/1988	II.A.2.	Text added
03/01/1988	II.B.3.	Text revised
03/01/1988	II.B.4.	Confidence statement revised
03/01/1988	II.C.3.	Text added
03/01/1988	II.C.4.	Confidence statement revised
06/30/1988	I.A.7.	Changed primary contact's telephone number
12/01/1988	II.A.3.	van Durren et al. citation year corrected
04/01/1989	I.A.	Oral RfD summary noted as pending change
12/01/1989	I.B.	Inhalation RfD now under review
03/01/1990	II.	Clarified NTP, 1982 citation
03/01/1990	VI.	Bibliography on-line
01/01/1991	II.	Text edited
01/01/1991	II.C.1.	Inhalation slope factor removed (global change)

02/01/1991	II.C.3.	Information on extrapolation process included
08/01/1991	VI.A.	References clarified
08/01/1991	VI.C.	References clarified
01/01/1992	IV.	Regulatory actions updated
08/01/1995	I.A., I.B.	EPA's RfD/RfC and CRAVE workgroups were discontinued in May, 1995. Chemical substance reviews that were not completed by September 1995 were taken out of IRIS review. The IRIS Pilot Program replaced the workgroup functions beginning in September, 1995.
04/01/1997	III., IV., V.	Drinking Water Health Advisories, EPA Regulatory Actions, and Supplementary Data were removed from IRIS on or before April 1997. IRIS users were directed to the appropriate EPA Program Offices for this information.
01/12/2000	I., II.	This chemical is being reassessed under the IRIS Program.
08/13/2002	I-VIII	New RfD, RfC, and cancer assessment
10/28/2003	I.A.6., I.B.6., II.D.2.	Screening-Level Literature Review Findings message has been added.
06/22/2005	I.A.6., I.B.6., II.D.2.	Screening-Level Literature Review Findings message has been removed and replaced by comprehensive literature review conclusions.

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_VIII. Synonyms

Substance Name — 1,1-Dichloroethylene
CASRN — 75-35-4
Last Revised — 08/13/2002

- 1,1-Dichloroethene
- 1,1-DCE
- Dichloroethene, 1,1-
- Ethylene, 1,1-dichloro-
- NCI-C54262
- RCRA Waste Number U078
- Sconatex
- UN 1303
- Vinylidene chloride
- Vinylidene dichloride
- Vinylidine chloride
- Chlorure de vinylidene
- VDC

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- Principal and Supporting Studies
- Uncertainty and Modifying Factors
- Additional Studies/Comments
- Confidence in the Oral RfD
- EPA Documentation and Review

Reference Concentration for Chronic Inhalation Exposure (RfC)

- Inhalation RfC Summary
- Principal and Supporting Studies
- Uncertainty and Modifying Factors
- Additional Studies/Comments
- Confidence in the Inhalation RfC
- EPA Documentation and Review

Carcinogenicity Assessment for Lifetime Exposure

Evidence for Human Carcinogenicity

- Weight-of-Evidence Characterization
- Human Carcinogenicity Data
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- Supporting Data for Carcinogenicity

Quantitative Estimate of Carcinogenic Risk from Oral Exposure

- Summary of Risk Estimates
- Dose-Response Data

Last updated on Tuesday, March 16, 2010

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Administrative Decisions Cited

Lancaster v. Dep't of Environment & Natural Resources, 04 EHR 1151.

Lucy, Inc. v. Dep't of Environment and Natural Resources, 01 EHR 1695.

Moore v. Dep't of Environment and Natural Resources, 06 EHR 1479

Sharpe v. Dep't of Environment & Natural Resources Environmental Management Commission, 03 EHR 1776.

Southerland Electric Company v. McLawhorn, 00 EHR 2090.

Wheatley Oil Company, Inc. v. Dep't of Environment & Natural Resources, 03 EHR 0030

SECTION .0200. CLASSIFICATIONS AND GROUNDWATER QUALITY STANDARDS

.0201 GROUNDWATER CLASSIFICATIONS

The classifications which may be assigned to the groundwaters will be those specified in the following series of classifications:

(1) Class GA groundwaters; usage and occurrence:

(a) Best Usage. Existing or potential source of drinking water supply for humans.

(b) Conditions Related to Best Usage. This class is intended for those groundwaters in which chloride concentrations are equal to or less than 250 mg/l, and which are considered suitable for drinking in their natural state, but which may require treatment to improve quality related to natural conditions.

(c) Occurrence. In the saturated zone.

(2) Class GSA groundwaters; usage and occurrence:

(a) Best Usage. Existing or potential source of water supply for potable mineral water and conversion to fresh waters.

(b) Conditions Related to Best Usage. This class is intended for those groundwaters in which the chloride concentrations due to natural conditions is in excess of 250 mg/l, but which otherwise may be considered suitable for use as potable water after treatment to reduce concentrations of naturally occurring substances.

(c) Occurrence. In the saturated zone.

(3) Class GC groundwaters: usage and occurrence:

(a) Best Usage. The best usage of GC groundwaters is as a source of water supply for purposes other than drinking, including other domestic uses by humans.

(b) Conditions Related to Best Usage. This class includes those groundwaters that do not meet the quality criteria for GA or GSA groundwaters and for which efforts to improve groundwater quality would not be technologically feasible, or not in the best interest of the public. Continued consumption of waters of this class by humans could result in adverse health affects.

(c) Occurrence. Groundwaters of this class may be defined by the Commission pursuant to Section .0300 of this Subchapter on a case by case basis.

History Note

Statutory Authority G.S. 143-214.1; 143B-282(2);
Eff. June 10, 1979;
Amended Eff. October 1, 1993; August 1, 1989; September 1, 1984; December 30, 1983.

.0202 GROUNDWATER QUALITY STANDARDS

(a) The groundwater quality standards for the protection of the groundwaters of the state are those specified in this Rule. They are the maximum allowable concentrations resulting from any discharge of contaminants to the land or waters of the state, which may be tolerated without creating a threat to human health or which would otherwise render the groundwater unsuitable for its intended best usage.

(b) The groundwater quality standards for contaminants specified in Paragraphs (g) and (h) of this Rule are as listed, except that:

(1) Where the standard for a substance is less than the practical quantitation limit, the detection of that substance at or above the practical quantitation limit constitutes a violation of the standard.

(2) Where two or more substances exist in combination, the Director shall consider the effects of chemical interactions as determined by the Division of Public Health and may establish maximum concentrations at values less than those established in accordance with Paragraphs (c), (g), or (h) of this Rule. In the absence of information to the contrary, in accordance with Paragraph (d) of this Rule, the carcinogenic risks associated with carcinogens present shall be considered additive and the toxic effects associated with non-carcinogens present shall also be considered additive.

(3) Where naturally occurring substances exceed the established standard, the standard shall

be the naturally occurring concentration as determined by the Director.

(c) Except for tracers used in concentrations which have been determined by the Division of Public Health to be protective of human health, and the use of which has been permitted by the Division, substances which are not naturally occurring and for which no standard is specified shall not be permitted in concentrations at or above the practical quantitation limit in Class GA or Class GSA groundwaters. Any person may petition the Director to establish an interim maximum allowable concentration for a substance for which a standard has not been established under this Rule. The petitioner shall submit relevant toxicological and epidemiological data, study results, and calculations necessary to establish a standard in accordance with Paragraph (d) of this Rule. Within three months after the establishment of an interim maximum allowable concentration for a substance by the Director, the Director shall initiate action to consider adoption of a standard for that substance.

(d) Groundwater quality standards for substances in Class GA and Class GSA groundwaters are established as the least of:

(1) Systemic threshold concentration calculated as follows: [Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)];

(2) Concentration which corresponds to an incremental lifetime cancer risk of 1x10–6;

(3) Taste threshold limit value;

(4) Odor threshold limit value;

(5) Maximum contaminant level; or

(6) National secondary drinking water standard.

(e) The following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in Paragraph (d) of this Rule.

(1) Integrated Risk Information System (U.S. EPA).

(2) Health Advisories (U.S. EPA Office of Drinking Water).

(3) Other health risk assessment data published by U.S. EPA.

(4) Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.

(f) Groundwater quality standards specified in Paragraphs (g) and (h) of this Rule and interim maximum allowable concentrations established pursuant to Paragraph (c) of this Rule shall be reviewed on a triennial basis. Appropriate modifications to established standards shall be made in accordance with the procedure prescribed in Paragraph (d) of this Rule where modifications are considered appropriate based on data published subsequent to the previous review.

(g) Class GA Standards. Where not otherwise indicated, the standard refers to the total concentration in micrograms per liter of any constituent in a dissolved, colloidal or particulate form which is mobile in groundwater. This does not apply to sediment or other particulate matter which is preserved in a groundwater sample as a result of well construction or sampling procedures. The Class GA standards are:

(1) Acenaphthene: 80;

(2) Acenaphthylene: 200;

(3) Acetone: 6 mg/L;

(4) Acrylamide: 0.008;

(5) Anthracene: 2 mg/L;

(6) Arsenic: 10;

(7) Atrazine and chlorotriazine metabolites: 3;

(8) Barium: 700;

(9) Benzene: 1;

(10) Benzo(a)anthracene (benz(a)anthracene): 0.05;

(11) Benzo(b)fluoranthene: 0.05;

(12) Benzo(k)fluoranthene: 0.5;

(13) Benzoic acid: 30 mg/L;

(14) Benzo(g,h,i,)perylene: 200;

(15) Benzo(a)pyrene: 0.005;

(16) Bis(chloroethyl)ether: 0.03;

(17) Bis(2–ethylhexyl) phthalate (di(2–ethylhexyl) phthalate): 3;

(18) Boron: 700;

(19) Bromodichloromethane: 0.6;

(20) Bromoform (tribromomethane): 4;

(21) n-Butylbenzene: 70;

(22) sec-Butylbenzene: 70;

(23) tert-Butylbenzene: 70;

(24) Butylbenzyl phthalate: 1 mg/L;

(25) Cadmium: 2;

(26) Caprolactam: 4 mg/L;

(27) Carbofuran: 40;

(28) Carbon disulfide: 700;

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September 28, 2004

Mr. David Hance
Division of Water Quality
North Carolina Department of Environment and Natural Resources
1636 Mail Service Center
Raleigh, North Carolina 27699-1636

Re: Rhodia Inc./Comments on Proposed Revision to North Carolina Groundwater Quality Standard for 1,1-Dichloroethylene
Client-Matter No. 4066081.000602

Dear Mr. Hance:

We represent Rhodia, Inc., a global specialty chemicals manufacturer. The purpose of this letter is to comment on the North Carolina Department of Environment and Natural Resources' (NCDENR's) proposed changes to the 2L groundwater standards, specifically the proposed change and subsequent rescission of the change to the standard for 1,1-dichloroethylene (1,1-DCE).

For almost a decade now, Rhodia has been operating a groundwater remediation system at its former facility in Gastonia. The primary contaminant is 1,1-DCE.

As part of its remediation, Rhodia paid nearly $1 million to provide municipal water to over 100 residences in the surrounding area, thus significantly reducing the risk posed by this site. The remediation system also prevents contaminated groundwater from discharging to an unnamed tributary on Rhodia's former site. This risk reduction is enhanced as there is no public access to the tributary. The closest access point is downstream of the site where contamination from an off-site, non-Rhodia source not being remediated poses the risk of exposure. The continued operation of the groundwater remediation system continues to further reduce the risk through the ongoing removal of contaminant mass.

The clean up standard Rhodia has been striving to meet for 1,1-DCE has been the historic 2L standard of .007 milligrams per liter (mg/L). Last year, the United States Environmental Protection Agency ("U.S. EPA") published its findings on its reevaluation of various compounds. As to 1,1-DCE, U.S. EPA concluded that the risks had been greatly overstated. In light of U.S. EPA's findings, one would have expected the 2L standard for 1,1-DCE to have been raised. Needless to say,

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September 28, 2004
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NCDENR's proposal to tighten the 2L standard from .007 mg/L to 5.8×10^{-5} mg/L was both surprising and unjustified.

NCDENR has now correctly proposed to rescind this proposed reduction. However, keeping the current standard is not legally sufficient either. Rather, based upon its regulations, NCDENR must raise this standard so it is based on current, accurate toxicological data.

Two regulations govern the establishment of groundwater quality standards in North Carolina. First, under 15A N.C.A.C. 2L.0202(d), the lesser of six different standards is to be used to set a compound's groundwater limit. Second, 15A N.C.A.C. 2L.0202(e) requires NCDENR to establish groundwater standards based upon four sources of toxicity data listed "in order of preference" in the regulation. Although separate, 15A N.C.A.C. 2L.0202(d) and (e) are not independent regulations. Rather they must be read in tandem as the sources for establishing standards listed in 15A N.C.A.C. 2L.0202(e) must **"correspond to levels described in Paragraph (d) of this Rule."** (Emphasis added.) From this it follows that if a basis for a groundwater quality standard listed in 15A N.C.A.C. 2L.0202(d) does not "correspond" to an accepted reference source listed in 15A N.C.A.C. 2L.0202(e), then the standard in subparagraph (d) cannot be used.

That is the current situation with regard to 1,1-DCE. On its face, the "lesser" of the six identified standards in 15A N.C.A.C. 2L.0202(d) for 1,1-DCE is the maximum contaminant level (MCL) of .007 mg/L. The Safe Drinking Water Act requires that determination of an MCL for a compound must be based in part on the oral reference dose (RfD) for that compound. In its reevaluation of 1,1-DCE in August 2002, U.S. EPA recalculated the RfD for 1,1-DCE, changing it from 0.009mg/kg-day to 0.046mg/kg-day. U.S. EPA published these changes as part of its revision to the file for 1,1-DCE on the Integrated Risk Information System (IRIS). Pursuant to 15A N.C.A:C. 2L.0202(e), IRIS is the most preferred reference source for the establishment of groundwater quality standards.

For reasons of workload, administrative costs and lack of evidence of public cost savings, U.S EPA decided not to change the MCL for 1,1-DCE despite its revision to IRIS. (See <u>National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Water Standards</u>, 68 Fed. Reg. 42,908, 42,921 (July 18, 2003)). As a result, for non-scientific reasons, the current MCL for 1,1-DCE no longer "corresponds" to the IRIS evaluation of 1,1-DCE. Thus, under North Carolina regulations, the current MCL cannot be used to establish the 2L groundwater quality standard for 1,1-DCE.

15A N.C.A.C. 2L.0202(d) provides that groundwater quality standards can also be the lesser of the following for a compound:

1. Systemic threshold concentration;
2. Concentration corresponding to a 1X10 –6 incremental lifetime cancer risk;
3. Taste threshold limit value;

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4. Odor threshold limit value; or
5. National secondary drinking water standard.

1,1-DCE does not have a taste threshold limit value, odor threshold limit value or national secondary drinking water standard. Since in its IRIS revisions U.S. EPA removed the oral cancer slope factor for 1,1-DCE, there is no cancer risk concentration that can be used to establish a groundwater quality standard.

Thus, the only basis for establishing a groundwater quality standard for 1,1-DCE is the systemic threshold concentration for 1,1-DCE. According to 15A N.C.A.C. 2L.0202(d)(1), the systemic threshold concentration is calculated as follows:

> Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution [(.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)]

Since this formula can use U.S. EPA's recalculated reference dose (RfD) for 1,1-DCE, the systemic threshold concentration "corresponds" with IRIS and thus complies with 15A N.C.A.C. 2L.0202(e). Performing the calculation using the recalculated RfD, the systemic threshold concentration for 1,1-DCE is .322 mg/L, nearly 50 times higher than the current 2L standard.

At least at groundwater remediation sites and no doubt more generally, making this change in the 1,1-DCE standard would likely improve environmental quality in North Carolina. Rhodia has been operating a traditional pump-and-treat remediation system at its former Gastonia site for nearly a decade. During that time, it has continually evaluated the feasibility of other remedial options for the site. However, none of these options has proved viable as each option identified would have involved significant cost increases without corresponding reductions in the amount of time needed to reach the current .007 mg/L standard. With a revised standard, clean up can be achieved quicker, making it more likely that Rhodia will consider changes that would result in a faster rate of clean up than is currently occurring. That would clearly be a benefit to North Carolina's environment.

In responding to a previous comment on this proposed change, NCDENR noted that groundwater quality standards can be based on "other appropriate, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data", citing 15A N.C.A.C. 2L.0202(e)(4) as support for this position. While 15A N.C.A.C. 2L.0202(e)(4) allows for other appropriate risk assessment data to be used to establish groundwater quality standards, it is "in order of preference" the least favored reference source. Furthermore, NCDENR has not cited the "other appropriate, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data" on which it is supporting its decision.

IRIS is the most preferred source. If it can be used, it must be used. With regard to establishing a groundwater quality standard for 1,1-DCE, IRIS can be used through the calculation of

Mr. David Hance
September 28, 2004
Page 4

the systemic threshold value. As a result, pursuant to 15A N.C.A.C. 2L.0202(d) and (e), NCDENR must raise the groundwater quality standard for 1,1-DCE to .322 mg/L. If it fails to do so, NCDENR is failing to act as required by rule, acting erroneously, and acting arbitrarily and capriciously, all of which expose the agency to a likely successful administrative challenge to its action under N.C. Gen. Stat. § 150B-23(a)(2), (4), and (5). NCDENR should seriously reevaluate its position in light of the comments set forth in this letter.

Sincerely,

HELMS MULLISS & WICKER, PLLC

Benne C. Hutson

cc: Rhodia Management Team

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ENVIRONMENTAL

Mr. David Hance
Groundwater Section
Division of Water Quality
Department of Environment and Natural Resources
1636 Mail Service Center
Raleigh, NC 27699-1636

Subject:
1,1-Dichloroethene

Date:
13 September 2004

Contact:
Shawn Sager

Phone:
Ext. 225

E-mail:
ssager@arcadis-us.com

Our ref:
NC102014.0001

Dear Mr. Hance:

During our meeting on Thursday, August 29, you stated that the comment period for the proposed changes to the 2L Groundwater Standards remained open. The focus of this letter is the substance 1,1-dichloroethene or 1,1-dichloroethylene as it is referenced in the rule. Craig A. Bromby of the law firm of Hunton & Williams has collaborated with me on the preparation of the comments contained herein.

The proposed reduction in the 2L standard from 0.007 milligrams per liter (mg/L) to 5.8×10^{-5} mg/L is inappropriate. On August 13, 2002, the U.S. Environmental Protection Agency (USEPA) revised the file for 1,1-dichloroethene on the Integrated Risk Information System (IRIS) database (URL: www.epa.gov/iris) (URL for 1,1-dichloroethene: http://www.epa.gov/iris/subst/0039.htm). The reevaluation of 1,1-dichloroethene resulted in the removal of the oral cancer slope factor and the recalculation of the oral reference dose. The result is that if the 2L standard were recalculated using the latest revised toxicity values, it would be much higher than the existing standard, as seen below.

Calculation Of A Groundwater Standard Following 15A NCAC 2L .0202

1. Systemic threshold concentration: Oral reference dose revised on August 13, 2002.

   RfD = 5×10^{-2} mg/kg-day

   Systemic threshold concentration = RfD × 70 kg × 0.2/2 L/day

   Systemic threshold concentration = (5×10^{-2} mg/kg-day × 70 kg × 0.2)/2 L/day
   = 0.350 mg/L

Mr. David Hance
13 September 2004

2. Concentration corresponding to an incremental lifetime cancer risk of 1×10^{-6} is not calculated because there is no oral cancer slope factor on IRIS (as of August 13, 2002, when the old value was withdrawn by the USEPA due to a reevaluation of the toxicity information).

3. Taste threshold: none found.

4. Odor threshold: none found.

5. Maximum contaminant level: 0.007 mg/L.

6. Secondary maximum contaminant level: none listed.

Based on the literal application of 15A NCAC 2L .0202(e), the standard for 1,1-dichloroethene should remain at 0.007 mg/L. However, it is apparent from the revision to the information contained in the IRIS file for this compound that a standard of 0.007 mg/L for 1,1-dichloroethene is inappropriately stringent, since the systemic threshold concentration is calculated as 0.35 mg/L. The changes in the IRIS file for this constituent demonstrate a flaw in the hierarchy used to develop the 2L standards, as discussed below.

It is incumbent on the Division of Water Quality to propose a change to 15A NCAC 2L .0202(e) to require, rather than a rote reliance on the lowest number, notwithstanding its validity, that the best scientific information available be used to achieve an appropriately protective level, which reflects the actual risk posed by the constituent. Proposal of a standard any lower than 0.007 mg/L, given this information, both violates 15A NCAC 2L .0202 and is without valid scientific basis. Allowing the standard to remain at 0.007 mg/L is only marginally more justifiable, and should be corrected now or at the latest in the next biennial review.

We propose that the 15A NCAC 2L .0202(d) be amended to allow the selection of the most scientifically defensible value among the sources listed rather than the lowest value, and that 15A NCAC 2L .0202(e) be amended to provide that the derivation of the appropriate protective level be guided by the references included in 15A NCAC 2L .0202(e) according to the scientific validity of the reference rather than proceeding in a particular order of preference. The data developed for 1,1-dichloroethene demonstrate that a more dynamic system is needed in this area.

Groundwater standards are used to set clean-up levels for contaminated sites. Overly stringent levels set orders of magnitude too low can result in the needless expenditure of public and private resources for no justifiable reason. Standards based on outdated information, particularly when the invalidity of the information has been acknowledged by the agency on whom the rule presently directs you to rely, cannot be justified and as a matter of sound public policy, should not be allowed to stand.

The case of 1,1-dichloroethene plainly illustrates the flaw in the existing regulation, which the division should seek to correct. The correction will not jeopardize public health or the quality of the environment, as in many, if not most, cases the lowest number may still reflect the most scientifically sound value. Since the groundwater standards do not necessarily apply to public water supplies, relying on a maximum contaminant level (MCL) that has not been reevaluated based on current toxicity information, may be inappropriate. Additionally, it is unsuitable for the EMC to adopt a standard that is not supported by the most recent and reliable data, and relies instead on a historical published artifact.

We urge you to reconsider your position regarding the proposed reduction in the 2L standard. Based on the most up-to-date information presented herein, the standard should be recalculated. If you have any questions, please feel welcome to contact the undersigned or Craig Bromby of Hunton & Williams.

Sincerely,

ARCADIS G&M of North Carolina, Inc.

Shawn L. Sager, Ph.D.
Principal Scientist

Copies:
Carl Bailey—NCDENR
Arthur Mouberry—NCDENR
Steve Olp—Celanese
Craig Bromby—Hunton & Williams

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Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

October 1, 2004

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Dear Mr. Hance, Mr. Martin, and Mr. Pitner:

I am writing in response to the comments received today on thirty-three groundwater quality standards that recently went to public hearing on August 19. The detailed responses to comments are attached. Based on review of the comments, I am recommending changes to cyanide and 1,1-dichloroethylene that were not mentioned by me at the public hearing at the August 19 public hearing.

- For cyanide, I am recommending a change in the descriptive narrative from cyanide (as free cyanide or hydrogen cyanide) to cyanide (as free cyanide).

- For 1,1-dichloroethylene, I am recommending an increase in the standard for 1,1-dichloroethylene from 0.007 mg/L to 0.35 mg/L. Using the new 2002 data provided by US EPA, the recommended groundwater quality standard for 1,1-dichloroethylene is 0.35 mg/L instead of 0.007 mg/L. However, the lesser of the 1-6 criteria specified in 15A NCAC 2L .0202 (d) is 0.007 mg/L, the US EPA maximum contaminant level. The 0.007 mg/L meets the criteria of the rule (as being the lesser of the six criteria) but the 0.35 mg/L is the more scientifically valid level.

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Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

October 1, 2004 letter
Mr. Hance
Mr. Martin
Mr. Pitner

Please do not hesitate to call me if you have any questions at 919-715-6429.

Sincerely,

Dr. Luanne K. Williams, Toxicologist
Occupational and Environmental Epidemiology Branch
NC Division of Public Health

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1,1-dichloroethylene

September 30, 2004 Comments from Mr. Charles R. Wakild with Progress Energy – Progress Energy questions why the 0.000058 mg/L was stated as the recommended level in the August 19 public hearing notice instead of the US EPA maximum contaminant level goal and maximum contaminant level of 0.007 mg/L.

September 28, 2004 comments from Benne C. Hutson with Helms Mulliss Wicker – questions were raised as to why the outdated US EPA maximum contaminant level of 0.007 mg/L is being recommended as opposed to the systemic threshold concentration of 0.35 mg/L which was calculated using the revised reference dose.

NC Division of Public Health Response to Comments

Response to Progress Energy Comments

The August 19 public hearing notice did not have the correct or latest NC Division of Public Health recommended groundwater quality standard for 1,1-dichloroethylene of 0.007 mg/L. In 2002, the NC Division of Public Health forwarded new recommendations to the Groundwater Section (see enclosed memorandum) regarding 1,1-dichloroethylene. The new recommended level was 0.007 mg/L which was an increase from the previously recommended level of 0.000058 mg/L made in 1999. The 0.000058 mg/L corresponded to a one in a million cancer risk based on the US EPA recommended oral slope factor of 0.6 $(mg/kg\text{-}day)^{-1}$. The 0.007 mg/L level is the lesser of the six criteria used to calculate the standards as mentioned in 15A NCAC 2L .0202(d).

Response to Helms Mulliss Wicker Comments

In August 2002, US EPA completed a review of the noncancer and carcinogenicity studies which resulted in revision to the oral reference dose and carcinogenic assessment but not the maximum contaminant level. The previous chronic oral reference dose was 0.009 mg/kg-day based on hepatic lesions in rats observed in the 1983 Quast et al. study. This reference dose served as the basis for the calculation of the existing maximum contaminant level as follows (see 1995 IRIS):

0.009 mg/kg-day x 70 kg x 1 day/2 Liters x 0.10 safety factor account for carcinogenicity x 0.20 relative source contribution = 0.0063 mg/L or rounded up to 0.007 mg/L

According to US EPA's 2002 assessment, there is no statistically or biologically significant increase in tumor incidence at any site in the relevant oral bioassays. Therefore, a safety factor of 10 to account for carcinogenicity is no longer needed. US EPA also conducted additional review of the 1983 Quast et al. study and changed the reference dose based on this review from 0.009 mg/kg-day to 0.05 mg/kg-day. Using this revised chronic oral reference dose, a systemic threshold concentration can be calculated as follows:

A systemic threshold concentration for 1,1-dichloroethylene can be calculated as shown (US Environmental Protection Agency, Integrated Risk Information System (IRIS) On-line Computer Database 2004 http://www.epa.gov/iris):

0.05 mg/kg/day x 70 kg x 1day / 2L x 0.20(RSC) = 0.35 mg/L
RSC = Relative Source Contribution

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1,1-dichloroethylene

Note: The oral reference dose of 0.05 mg/kg-day is based upon a rat chronic drinking water study where liver toxicity was the critical effect reported.

Using the new 2002 data provided by US EPA, the recommended groundwater quality standard for 1,1-dichloroethylene is 0.35 mg/L instead of 0.007 mg/L. However, the lesser of the 1-6 criteria specified in 15A NCAC 2L .0202 (d) is 0.007 mg/L, the US EPA maximum contaminant level. The 0.007 mg/L meets the criteria of the rule but the 0.35 mg/L is the more scientifically valid level. It is recommended to use the more scientifically valid level of 0.35 mg/L which is calculated as follows:

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1,1-dichloroethylene

Criteria Specified in 15A NCAC 2L .0202

1. A systemic threshold concentration for 1,1-dichloroethylene can be calculated as shown (US Environmental Protection Agency, Integrated Risk Information System (IRIS) On-line Computer Database 2004 http://www.epa.gov/iris):

   0.05 mg/kg/day x 70 kg x 1day / 2L x 0.20(RSC) = 0.35 mg/L

   RSC = Relative Source Contribution
   Note: The oral reference dose of 0.05 mg/kg-day is based upon a rat chronic drinking water study where liver toxicity was the critical effect reported.

2. According to US EPA, there is no statistically or biologically significant increase in tumor incidence at any site in the relevant oral bioassays. Using the draft revised guidelines for carcinogenic risk assessment, US EPA characterizes the carcinogenic weight of evidence as inadequate and accordingly chose not to derive an oral slope factor (US Environmental Protection Agency, Integrated Risk Information System (IRIS) On-line Computer Database 2004 http://www.epa.gov/iris). The 2002 (8/13/02) IRIS summary replaces the 1985 summary where a slope factor was generated from two studies that did not show statistically significant increases in tumor incidence attributable to oral exposure. Under the 1999 draft revised guidelines for carcinogen risk assessment, EPA emphasizes the importance of using data that show a statistically significant increase in tumor incidence for calculating a slope factor. According to US EPA, the data for 1,1-dichloroethylene are inadequate for an assessment of human carcinogenic potential by the oral route, based on the absence of statistically or biologically significant tumors in limited bioassays in rats and mice balanced against the suggestive evidence in male mice in a single bioassay by inhalation and the limited evidence of genotoxicity. The human epidemiological results on the carcinogenicity of 1,1-dichloroethylene are too limited to draw useful conclusions. EPA concludes that the results of kidney tumors in one sex and one exposure in a single species of rodents are too limited to support an exposure-response assessment.

3. Currently, the maximum contaminant level for 1,1-dichloroethylene is 0.007 mg/L (U.S. Environmental Protection Agency Office of Ground Water and Drinking Water http://www.epa.gov/safewater/mcl.html 2004). The previous chronic oral reference dose available on IRIS was 0.009 mg/kg-day which was based on hepatic lesions in rats observed in the 1983 Quast et al. study. This reference dose served as the basis for the calculation of the existing maximum contaminant level as follows (see the 1995 IRIS):

0.009 mg/kg-day x 70 kg x 1 day/2 Liters x 0.10 safety factor account for carcinogenicity x 0.20 relative source contribution = 0.0063 mg/L or rounded up to 0.007 mg/L

This level is outdated. The 1983 Quast et al. study was reviewed by US EPA in 2002 and based on this review, US EPA recommended a change in the reference dose to 0.05 mg/kg-day. Also, according to US EPA, there is no statistically or biologically significant increase in tumor incidence at any site in the relevant oral bioassays and a safety factor of 10 is no longer needed to account for carcinogenicity. If US EPA used the same equation above to calculate a maximum contaminant level but removed the safety factor of 10 (which is no longer needed to account for carcinogenicity) and

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1,1-dichloroethylene

inserted the new reference dose of 0.05 mg/kg-day, then the maximum contaminant level may be calculated to be 0.35 mg/L.

4. Currently, there is no national secondary drinking water standard for 1,1-dichloroethylene (U.S. Environmental Protection Agency Office of Ground Water and Drinking Water http://www.epa.gov/safewater/mcl.html 2004).

5. A taste threshold value for 1,1-dichloroethylene was not found in the literature.

6. An odor threshold value for 1,1-dichloroethylene was not found in the literature.

The recommended groundwater quality standard for 1,1-dichloroethylene is 0.35 mg/L and not 0.007 mg/L.

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HELMS MULLISS WICKER

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January 18, 2005

VIA STANDARD MAIL

Mr. David H. Moreau
Chairman
Dpt. City & Planning, UNC-CH
CB3140
Chapel Hill, NC 27599

Re: Proposed Groundwater Standard for 1,1-dichloroethylene (1,1-DCE).
Client-Matter No. 4066081-602

Dear Mr. Moreau:

We represent Rhodia, Inc., a global specialty chemicals manufacturer. For almost a decade now, Rhodia has been operating a groundwater remediation system at its former manufacturing plant in Gastonia. The primary constituent of concern is 1,1-dichloroethylene (1,1-DCE).

We are writing regarding the proposed revision to the groundwater quality standard for 1,1-DCE that the EMC will consider at its February meeting. The regulatory situation regarding 1,1-DCE is different from all of the other chemicals you will consider in February. The current groundwater quality standard for 1,1-DCE is .007 mg/L. Based on U.S. EPA's most current scientific and toxicological evidence, DENR's toxicologist and the two hearing officers all agree that the standard should be .350 mg/L. (A copy of our September 28, 2004 letter explaining why the standard should be .350 mg/L and copies of Dr. Luanne K. Williams' letter and the portions of the hearing officers' report agreeing with this conclusion are enclosed.)

However, the hearing officers concluded that DENR's current regulations would have to be amended to make this change. As we will explain in this letter, we believe that the EMC can make this change under the current regulations and we ask that you do so at your February meeting.

Two regulations govern the establishment of groundwater quality standards.

1. 15A N.C.A.C. 2L .0202(d) provides that the lesser of six different standards should be used to set a compound's groundwater limit.

2. 15A N.C.A.C. 2L.0202(e) mandates that four sources of toxicity data listed "in order of preference shall be used in establishing" groundwater standards.

January 18, 2005
Page 2

Although separate, these two regulations are not independent of each other. Rather they must be read together as the sources listed in 15A N.C.A.C. 2L.0202(e) must "correspond to levels described in Paragraph (d) of this Rule." From this it follows that if a basis for a groundwater quality standard listed in 15A N.C.A.C. 2L.0202(d) does not "correspond" to an accepted reference source listed in 15A N.C.A.C. 2L.0202(e), then the standard in subparagraph (d) cannot be used.

That is the situation with regard to 1,1-DCE. On its face, the "lesser" of the six identified standards in 15A N.C.A.C. 2L.0202(d) for 1,1-DCE is the maximum contaminant level (MCL) of .007 mg/L. The Safe Drinking Water Act requires that determination of a compound's MCL be based in part on the oral reference dose (RfD) for that compound. In its reevaluation of 1,1-DCE in August 2002, U.S. EPA recalculated the RfD for 1,1-DCE, changing it from 0.009 mg/kg-day to 0.046 mg/kg-day. U.S. EPA published these changes as part of its revision to the file for 1,1-DCE on the Integrated Risk Information System (IRIS). Pursuant to 15A N.C.A.C. 2L.0202(e), IRIS is the most preferred reference source for the establishment of groundwater quality standards.

Even though it made changes to the IRIS file for 1,1-DCE, for reasons of workload, administrative costs and lack of evidence of public cost savings, U.S. EPA decided not to change the MCL for 1,1-DCE despite its revision to IRIS. (See enclosed copy of portions of National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Water Standards, 68 Fed. Reg. 42,908, 42,921 (July 18, 2003)). For non-scientific reasons, the current MCL for 1,1-DCE no longer "corresponds" to the IRIS evaluation of 1,1-DCE. Thus, under North Carolina regulations, the current MCL cannot be used to establish the 2L groundwater quality standard for 1,1-DCE.

15A N.C.A.C. 2L.0202(d) provides that groundwater quality standards can also be the lesser of the following for a compound:

1. Systemic threshold concentration;

2. Concentration corresponding to a $1X10^{-6}$ incremental lifetime cancer risk;

3. Taste threshold limit value;

4. Odor threshold limit value; or

5. National secondary drinking water standard.

1,1-DCE does not have a taste threshold limit value, odor threshold limit value or national secondary drinking water standard. In its reevaluation, U.S. EPA concluded that 1,1-DCE was not a carcinogen and removed the oral cancer slope factor for 1,1-DCE. Thus, there is no cancer risk concentration that can be used to establish a groundwater quality standard.

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Page 3

The only basis for establishing a groundwater quality standard for 1,1-DCE is the systemic threshold concentration for 1,1-DCE. According to 15A N.C.A.C. 2L.0202(d)(1), the systemic threshold concentration is calculated as follows:

> Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)]

Since this formula can use U.S. EPA's recalculated reference dose (RfD) for 1,1-DCE, the systemic threshold concentration "corresponds" with IRIS and thus complies with 15A N.C.A.C. 2L.0202(e). Performing the calculation using the recalculated reference dose, the systemic threshold concentration for 1,1-DCE is .350 mg/L.

Under the proposal before you in February, the groundwater quality standard for 1,1-DCE would continue to be the maximum contaminant level of .007 mg/L. From a scientific and toxicological basis, everyone agrees that this is not correct – rather, the groundwater quality standard for 1,1-DCE should be .350 mg/L. The express language of DENR's regulations for establishing groundwater quality standards mandates the same result – the groundwater quality standard for 1,1-DCE must be .350 mg/L. Please take appropriate action at your meeting in February to adopt this standard.

Sincerely,

HELMS MULLISS & WICKER, PLLC

Benne C. Hutson

Benne C. Hutson

Enclosures

cc: Robynn Moraites (w/o encls.)(via electronic mail)
Rhodia Management Team (w/o encls.)(via electronic mail)
Environmental Management Commission Members
Kevin Martin
Andrew Pitner
Frank Crawley
Dr. Luanne K. Williams
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Jeff Manning
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May 28, 2009

VIA OVERNIGHT MAIL
AND ELECTRONIC MAIL

Sandra Moore
North Carolina Department of
Natural and Environmental Resources
Division of Water Quality
Planning Section
1617 Mail Service Center
Raleigh, North Carolina 27699-1617

Re; Rhodia Inc., Radiator Specialty Company and Ashland Inc. / Comments on Proposed Amendments to North Carolina Groundwater Quality Standards – Legal Requirement to Amend Standard for 1,1-Dichloroethylene

Dear Ms. Moore:

We represent Rhodia Inc., Radiator Specialty Company and Ashland Inc. The purpose of this letter is to provide comments on the proposed changes to the North Carolina groundwater quality standards established by 15A N.C.A.C. 2L.0202(g). These comments are being provided on or before June 1, 2009, the deadline established for the submission of comments in the Notice of the Proposed Rule Amendments as published in the April 1, 2009 edition of the North Carolina Register.

The specific comment being submitted by Rhodia, Radiator Specialty and Ashland is that there is no proposed change to the groundwater quality standard for 1,1-dichloroethylene ("1,1-DCE"). Based upon applicable North Carolina statutes and regulations, including but not limited to 15A N.C.A.C. 2L.0202(d) and (e), the Environmental Management Commission ("EMC") has a mandatory legal obligation to amend the groundwater quality standard for 1,1-DCE from the current standard of 7 micrograms per liter (μg/L) to 350 μg/L as the current standard does not correspond to the United States Environmental Protection Agency's revised health risk assessment standard. A toxicologist with the Occupational Environmental Epidemiology Branch of the North Carolina Division of Public Health previously considered this matter in 2004 and recommended that the standard for 1,1-DCE be changed to 350 μg/L.

The full basis for this comment is set forth in the remainder of this letter.

I. Background

A. Rhodia

Rhodia formerly operated a specialty chemical manufacturing facility in Gastonia. For over a decade now, Rhodia has been operating a groundwater remediation system at this former facility. The primary contaminant of concern is 1,1-DCE.

As part of its remediation, Rhodia paid over $1 million to provide municipal water to over 100 residents in the surrounding area, thus significantly reducing the risks posed by this site. Operation of the remediation system has prevented and continues to prevent contaminated groundwater from reaching an unnamed tributary on Rhodia's former site. This risk reduction is enhanced as there is no public access to the tributary. The ongoing operation of the groundwater remediation system continues to further reduce the risks through the removal of contaminant mass.

Since 1997, Rhodia has been discharging its treated groundwater effluent to this unnamed tributary pursuant to the terms of an NPDES permit. In 2002, Rhodia received a determination from the Hazardous Waste Section of the Division of Waste Management that the treated effluent would not be characterized as a hazardous waste under the provisions of the Resource Conservation and Recovery Act ("RCRA"). This determination was based upon the finding, supported by years of sampling data, that the treated effluent did not contain levels of contaminants, including 1,1-DCE, that exceeded the lowest known health-based standards for those contaminants. As a result of this determination, the treated effluent now is primarily re-used in the manufacturing operations of the current owner of Rhodia's former facility with any amounts that cannot be used in the manufacturing process being discharged to the unnamed tributary pursuant to the terms of the NPDES permit.

B. Radiator Specialty

Radiator Specialty Company operates a manufacturing facility in Indian Trail, North Carolina. Since 1972, Radiator Specialty Company has manufactured and packaged various aerosol and liquid automotive and general purpose chemicals at this facility. In 1987, Radiator Specialty closed two former surface impoundments at the facility. In conjuction with these closure activities, Radiator Specialty initiated the process of applying for a post-closure permit to manage these closed impoundments in accordance with the requirements of RCRA. The initial post-closure permit was issued in 1996 and is currently going through the renewal process.

In 1994, prior to issuance of the permit, Radiator Specialty voluntarily designed and began operation of a groundwater remediation system. That system has been in continuous operation since that time with the treated effluent being discharged to a Union County publicly owned treatment works. One of the contaminants of concern is 1,1-DCE.

In 2003, Radiator Specialty received a determination from the Hazardous Waste Section of the Division of Waste Management that the treated effluent would not be characterized as a hazardous waste under the provisions of RCRA. The determination was based upon the finding, supported by years of sampling data, that the treated effluent did not contain levels of contaminants, including 1,1-DCE, that exceeded the lowest known health-based standards for those contaminants.

C. Ashland

Ashland has two former facilities in Greensboro and Raleigh where it has been voluntarily operating groundwater remediation systems for several years. In Greensboro, Ashland operated a distribution center for bulk industrial chemicals and solvents from 1968 to 2001. The Raleigh facility operated as a package warehouse and bulk distribution center from the late 1950s until bulk operations ceased in 1988. From that time, the Raleigh facility was used as a distribution warehouse until operations ceased in 2006. Both facilities have been sold to third parties. However, Ashland retains contractual responsibility for the historic contamination at each site.

At the Raleigh facility, Ashland has voluntarily been conducting investigation and remediation activities since 1989. This has included the operation of a groundwater extraction and treatment and a soil vapor extraction system. Similar work has been done at the Greensboro facility. 1,1-DCE is a contaminant of concern at both sites. Ashland is currently negotiating administrative orders on consent with the Hazardous Waste Section of the Division of Waste Management to govern future actions at both sites.

II. The History of the Standard for 1,1-DCE.

The cleanup standard each company has been striving to meet for 1,1-DCE in groundwater at each site has been the historic 2L standard of 7 μg/L. In 2003, the United States Environmental Protection Agency ("U.S. EPA") published its findings on the re-evaluation of risks posed by various compounds. As to 1,1-DCE, U.S. EPA concluded that the risk had been greatly overstated. As part of its re-evaluation, U.S. EPA recalculated the oral reference dose (RfD) for 1,1-DCE, changing it from 0.009 mg/kg/day to 0.050 mg/kg/day. U.S. EPA published these changes as part of its revision to the file for 1,1-DCE in the Integrated Risk Information System ("IRIS"). U.S. EPA subsequently reviewed the IRIS standard for 1,1-DCE on October 28, 2003 and June 22, 2005 and determined that these changes were still appropriate and no further revisions were necessary. (See Section VII. of U.S. EPA's current IRIS file for 1,1-DCE attached as Exhibit A.)

III. North Carolina Laws and Regulations Require that the Groundwater Standard for 1,1-DCE Be Changed from 7 μg/L to 350 μg/L.

In its proposed revisions to the 2L groundwater quality standards, the EMC and NCDENR have not proposed to make any change to the current standard for 1,1-DCE. Rather, the standard for 1,1-DCE would remain at 7 μg/L. However, keeping the 1,1-DCE standard the same violates North Carolina laws and regulations applicable to the establishment of groundwater quality standards. To comply with such statutory and regulatory requirements, the EMC and NCDENR must base the standard for 1,1-DCE on the most current and accurate toxicological data and, based upon that data, must increase the groundwater quality standard for 1,1-DCE to 350 μg/L.

A. 15A N.C.A.C. 2L.0202(d) and (e) – The North Carolina Regulations Governing the Establishment of Groundwater Quality Standards.

Two regulations govern the establishment of groundwater quality standards in North Carolina. First, under 15A N.C.A.C. 2L.0202(d), the lesser of six different standards is to be used to set a compound's groundwater limit. Second, 15A N.C.A.C. 2L.0202(e) requires the EMC and NCDENR to establish groundwater standards based upon four sources of toxicity data listed "in order of preference" in the regulation. Although separate, 15A N.C.A.C. 2L.0202(d) and (e) are not independent regulations. Rather, they must be read in tandem because the sources of toxicity data for establishing standards listed in 15A N.C.A.C. 2L.0202(e) must "**correspond to levels described in Paragraph (d) of this Rule**". (Emphasis added.) From this it follows that if a basis for a groundwater quality standard listed in 15A N.C.A.C. 2L.0202(d) does not "correspond" to an accepted reference source listed in 15A N.C.A.C. 2L.0202(e), then the standard in subparagraph (d) cannot be used. (For ease of reference, copies of these two regulations are enclosed with this letter as Exhibit B.)

This is the current situation with regard to 1,1-DCE. On its face, the "lesser" of the six identified standards in 15A N.C.A.C. 2L.0202(d) is the Federal Safe Drinking Water Act's maximum contaminant level ("MCL") of 7 μg/L. The Safe Drinking Water Act requires that determination of an MCL for a compound must be based in part on the oral reference dose (RfD) for that compound. In its re-evaluation of 1,1-DCE in 2003, U.S. EPA recalculated the RfD for 1,1-DCE, changing it from 0.009 mg/kg/day to 0.050 mg/kg/day. U.S. EPA published these changes as part of its revision to the file for 1,1-DCE in IRIS. (See Section I.A.1. of EPA's current IRIS file for 1,1-DCE attached as Exhibit A.) Pursuant to 15A N.C.A.C. 2L.0202(e), IRIS is the most preferred reference source for the establishment of groundwater quality standards.

For reasons of competing workload priorities, administrative costs and lack of evidence of public cost savings, U.S. EPA in 2002 decided not to change the MCL for 1,1-DCE despite its revision to IRIS. (See National Primary Drinking Water Regulations; Announcement of Completion of EPA's Review of Existing Water Standards, 68 Fed. Reg. 42908, 42921 (July 18, 2003) attached as Exhibit C). That situation remains the same today. As a result, for non-scientific and non-toxicological reasons, the current MCL for 1,1-DCE no longer "corresponds" to the IRIS evaluation of 1,1-DCE. Thus, under North Carolina regulations, the current MCL cannot be used to establish the 2L groundwater quality standard for 1,1-DCE.

B. Under 15A N.C.A.C. 2L.0202(d) and (e), the Groundwater Quality Standard for 1,1-DCE Must be 350 μg/L.

15A N.C.A.C. 2L.0202(d) provides that besides an MCL, groundwater quality standards can also be the lesser of the following for a compound:

1. Systemic threshold concentration;

2. Concentration corresponding to a 1 X 10^{-6} incremental lifetime cancer risk;

3. Taste threshold limit value;

4. Odor threshold limit value; or

5. National secondary drinking water standard.

1,1-DCE does not have a taste threshold limit value, odor threshold limit value or national secondary drinking water standard. In its IRIS revisions, U.S. EPA removed the oral cancer slope factor for 1,1-DCE and concluded that the compound was only a possible human carcinogen. As a result, there is no cancer risk concentration that can be used to establish a groundwater quality standard.

The only basis for establishing a groundwater quality standard for 1,1-DCE is the systemic threshold concentration for 1,1-DCE. According to 15A N.C.A.C. 2L.0202(d)(1), the systemic threshold concentration is calculated as follows:

> [Reference dose mg/kg/day x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganic; .20 for organics)] / [2 liters/day (avg. water consumption)]

Since this formula can use U.S. EPA's recalculated RfD for 1,1-DCE, the systemic threshold concentration "corresponds" with IRIS and thus complies with 15A N.C.A.C. 2L.0202(e). Performing the calculation using the recalculated RfD of 0.050 and a relative source contribution of .20 as 1,1-DCE is an organic compound, the systemic threshold concentration for 1,1-DCE is 350 μg/L, 50 times higher than the current 2L standard.

IV. Rhodia Made These Same Comments in 2004 and the State's Toxicologist Agreed that the Standard for 1,1-DCE Should Be 350 µg/L.

Rhodia brought these same points to the attention of the EMC and NCDENR in September 4, 2004 when the EMC last considered revisions to North Carolina's groundwater quality standards. Those comments were set forth in my letter to David Hance of the Division of Water Quality dated September 28, 2004. (A copy of this letter is attached as Exhibit D.) Similar comments had also been submitted by Dr. Shawn L. Sager, a principal scientist with Arcadis G&M of North Carolina, Inc. in a letter dated September 13, 2004. (A copy of this letter is included as Exhibit E.) These letters were reviewed by Dr. Luanne K. Williams, a toxicologist with the Occupational Environmental Epidemiology Branch of the North Carolina Division of Public Health. In comments enclosed with a letter dated October 1, 2004, Dr. Williams concluded that based upon the information provided in Rhodia's public comments, "**the recommended groundwater quality standard for 1,1-dichloroethylene is 350 µg/L and not 7 µg/L**." (Emphasis added.) A copy of Dr. Williams' letter is included as Exhibit F.

Despite the uncontroverted information presented in Rhodia's and Dr. Sager's 2004 public comments and the uncontroverted recommendation of Dr. Williams, the State's toxicologist, the 2004 hearing officers recommended that the standard for 1,1-DCE remain the same, erroneously concluding that the groundwater quality regulations in 15 N.C.A.C. Subchapter 2L would have to be amended in order for the 1,1-DCE standards to be changed. To the contrary, the regulations as they existed at that time required (as previously explained in this letter) that the standard for 1,1-DCE had to be changed to 350 µg/L. Rhodia presented this position to Dr. David H. Moreau, who was then chairman of the EMC, in a January 18, 2005 letter. (A copy of that letter is attached as Exhibit G.) Even though North Carolina's toxicologist agreed and North Carolina law and regulations required that the groundwater quality standard for 1,1-DCE had to be set at 350 µg/L, the EMC did not make that change but rather kept the standard at 7 µg/L.

V. U.S. EPA Has Changed the National Recommended Water Quality Criteria for 1,1-DCE Based on the Change in the RfD.

As previously stated, for non-scientific reasons U.S. EPA has not changed the drinking water standard for 1,1-DCE. However, U.S. EPA, based upon its 2003 revised risk assessment, has changed the recommended surface water quality standard for 1,1-DCE. On December 31, 2003, U.S. EPA published changes to the national recommended water quality criteria for the protection of human health for 15 compounds including 1,1-DCE. 68 Fed. Reg. 75507 (December 31, 2003). These criteria are numeric values that describe ambient water concentrations that protect human health from the harmful effects of pollutants. According to U.S. EPA, "these criteria are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects." 68 Fed. Reg. 75509.

At the time these changes were published, the water quality criteria for 1,1-DCE was 0.057 μg/L. In the revisions to the criteria for 1,1-DCE, U.S. EPA "incorporated into the recalculations . . . a new reference dose (RfD)" of 0.050 mg/kg/day. 68 Fed. Reg. 75510. This was the revised RfD that EPA published in its re-evaluation of the risk posed by 1,1-DCE. Based on the use of this revised RfD, the national recommended water quality criteria for 1,1-DCE went from 0.057 μg/L to 330 μg/L, an increase of nearly 6,000 times the previous standard. That revised standard remains in effect today. (A copy of the December 31, 2003 revisions to the national recommended water quality criteria is attached as Exhibit H.)

VI. Conclusion

The legal and regulatory situation regarding 1,1-DCE remains the same today as it did the last time the EMC considered revisions to North Carolina's groundwater quality standards. Under applicable North Carolina laws and regulations, specifically 15A N.C.A.C. 2L.0202(d) and (e), the EMC and NCDENR must change the groundwater quality standard for 1,1-DCE to 350 μg/L. If they fail to do so, the EMC and NCDENR are failing to act as required by law and are acting erroneously. Furthermore, since they had the same information in 2004 and failed then to take the legally required action and since they are being presented with the same information and legal standards today, if the EMC and NCDENR do not make this change to the standard this time, they will be acting arbitrarily and capriciously. All of these form a basis which expose the EMC and NCDENR to a successful administrative challenge to their failure to act under the North Carolina Administrative Procedure Act. To avoid such a challenge, the EMC and NCDENR must change the groundwater quality standard for 1,1-DCE from 7 μg/L to 350 μg/L.

Sincerely,

McGuireWoods LLP

Benne C. Hutson

Benne C. Hutson

Enclosures

cc: Rhodia Management Team (w/encls.)
Radiator Specialty Management Team (w/encls.)
Ashland Management Team (w/encls.)

\9117632.1

STATE OF NORTH CAROLINA
DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES

REPORT OF PROCEEDINGS TO THE NORTH CAROLINA ENVIRONMENTAL MANAGEMENT COMMISSION FOR THE PROPOSED REVISIONS TO THE 15A NCAC 02L .0202 GROUNDWATER QUALITY STANDARDS

PUBLIC HEARINGS

April 21, 6:30 PM – Western Piedmont Community College – Moore Hall, 1001 Burkemont Avenue, Morganton

April 23, 6:30 PM – Bladen Community College – Multipurpose Auditorium Building, 7418 Highway 41 West, Dublin

April 30, 6:30 PM – Archdale Building, Ground Floor Hearing Room, 512 N. Salisbury Street, Raleigh

Noting that this information could be of great importance to clearly identifying the human risk, staff agrees that maintaining the current standard would be adequately protective of public health until EPA's toxicological review is finalized.

1,1 DICLOROETHYLENE (1,1-DCE)
Proposed Standard: 7 ug/L
Current Standard: 7 ug/L

26. *__Comments received in regard to the 1,1,-dichloroethylene standard from McGuireWoods LLP (Benne C. Hutson) representing Rhodia Inc., Radiator Specialty Company and Ashland, Inc.__*

There is no proposed change to the groundwater quality standard for 1,1-dichloroethylene. Based upon applicable North Carolina statutes and regulations, including but not limited to 15A N.C.A.C. 2L.0202 (d) and (e), the Environmental Management Commission ("EMC") has a mandatory legal obligation to amend the groundwater quality standard for 1,1-DCE from the current standard of 7 micrograms per liter (ug/L) to 350 ug/L as the current standard does not correspond to the United States Environmental Protection Agency's revised health risk assessment standard. A toxicologist with the Occupational Environmental Epidemiology Branch of the North Carolina Division of Public Health previously considered this matter in 2004 and recommended that the standard for 1,1-DCE be changed to 350 ug/L.(See letter for further detail)

15A NCAC 2L .0202(d) and (e) although separate are not independent regulations. The sources of toxicity data for establishing standards listed in .0202(e) must "correspond to levels described in paragraph (d) of this Rule". The USEPA has not changed the MCL due to competing workload priorities, administrative cost and lack of evidence of pubic cost savings despite its revision of the oral reference dose from 0.009 mg/kg/day to 0.050 mg/kg/day in the IRIS database. The IRIS database is listed in .0202(e) as the preferred reference for toxicity values..

By not amending the standard to the lowest known health based-standard, the EMC and DENR are failing to act as required by law and are acting erroneously. Further, they are acting arbitrarily and capriciously and may expose themselves to a successful administrative challenge to their failure to act under the NCAPA.

__Response:__ DENR regulations require that groundwater standards be established in accordance with 15A NCAC 021 .0202 (d)-- the least of the six criteria.

The first two criteria, a systemic threshold concentration and a concentration corresponding to an incremental lifetime cancer risk of one-in-a-million, are concentrations calculated by DENR using the references cited in .0202 (e). The remaining four criteria used to establish a groundwater standard--taste threshold, odor threshold, the federal maximum contaminant level and the National secondary drinking water standard-- are concentrations that have been developed and are referenced in the literature.

EPA establishes the Federal Primary Drinking Water Standards and Secondary Drinking Water Standards according to federal regulations. The references set out in 15A NCAC 02L .0202 (e) are intended for DENR use when calculating the criteria in accordance with 15A NCAC 02L .0202 (d)(1) and (d)(2).

This issue led to a Groundwater Stakeholder Work Group, made up of industry, environmental groups and DENR agencies that met between July 14, 2005 and December 1, 2005. The Stakeholder Group, led by Carl Bailey, DWQ, and Kevin Martin, EMC, discussed needed changes to the groundwater rules to update groundwater standards so that the most up-to-date toxicity information was being incorporated. In the end, the EMC Groundwater Committee decided not to propose any changes to the groundwater rules stating that the 1,1,-DCE issue could be dealt with using the variance process (Attachment A-20).

VIII. RECOMMENDATIONS

Following a careful and comprehensive review of all of the submitted written and oral comments, supporting data, and attachments to this record, the Hearing Officers recommend that the North Carolina Environmental Management Commission adopt the changes to the groundwater quality standards as proposed with the following modifications:

1) Based on information obtained from the US EPA (Office of Water), comments, concerns and implementation issues noted during the public hearing process, the Hearing Officers (HOs) and staff recommend adoption of an arsenic standard at 10 ppb rather than the 0.02 ppb proposed. This recommendation is based upon the following information.

   According to the US EPA chemical manager for the inorganic arsenic assessment in the Office of Water, the final draft Toxicological Review for Inorganic Arsenic has been completed recently and is scheduled for public release in the near future. This latest assessment contains toxicity indices based on lung and bladder cancers. These internal cancers also served as endpoints for the Arsenic Rule in 2001 which established the Federal Drinking Water Standard of 10 ug/L. The available assessment in IRIS is based solely on skin cancer and does not address the known lung and bladder cancer risk.

   The Federal Drinking Water Standard of 10 ppb is considered by EPA to be protective of human health in drinking water sources. The HOs recommend that under 15A NCAC 02L .0103, establishment of a standard for arsenic at 10 ppb meets the Commission's policy for protection of the groundwater as a drinking water source and establishes a level that is protective of public health.

   The HOs make note here that a substantial number of comments were received from concerned parties with respect to the proposed arsenic level. The overwhelming majority disapproved of the proposed level due to the significant financial burden compliance would place on them at this time. Concerned parties also noted issues with naturally-occurring background levels that range from non-detect (practical quantitation limit at 1 ppb) to 190 ppb across the state. Of note, laboratories routinely detect and quantitate arsenic at approximately 1 - 2 ppb.

A-20 EMC Groundwater Committee 1,1-DCE Recommendation

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GWC Agenda Search

1996 to Present

Date 7/12/2006

Agenda Title Recommendation that the EMC use existing Subchapter 2L Rules to Resolve conflicts between Criteria in 15A NCAC 2L.0202 (d) and (e)

Type

Action

GWC Action The GWC unamimoulsy accepts & concurs with the Division recommendation that in individual site specific cases where there is a difference between 2L.0202 (d)(1) requirements in the 2L.0202 Groundwater Standards and the Federal MCLs, a variance under 2L.0113 could be approved that would allow less restrictive Groundwater Quality Standards while providing the site specific requirements necessary to protect Public Water Supplies

Incident Number

Location 711D

Date 5/9/2007

Agenda Title INFORMATION--Results from the Groundwater Standards Stakeholders Process- Stakeholders Recommendations regarding the use of Federal MCLs as NC groundwater standards & the modification of the Relative Source Contribution component in 2L.0202(d)(1)

Type

Information

GWC Action

Incident Number

Location 711D

Table 8
Summary of Remedial Technologies
207 Telegraph Drive, Gastonia, North Carolina

Containment	
Hydraulic	Five groundwater extraction wells currently operating; providing plume containment and mass reduction.
Physical Barriers (Slurry wall, grouting)	Not practical to install slurry walls as deep as needed. Grouting is possible but not likely to be completely effective. Would address migration through bedrock fractures.
Permeable Reactive Barriers (Zero Valent Iron, bio, e-barriers)	Depth is too great and would be difficult to install into the bedrock.
Phytoremediation	Depth is too great.
Source Zone Restoration/Partial Mass Removal	
Electrical Resistive Heating (three-phase or six-phase heating)	Installation of electrodes into the bedrock paired with a vapor extraction system. Resistive heating would "boil off" the VOCs, which would then be captured and treated. High potential for removing a significant mass of DNAPL. Installation into the bedrock would be technically challenging and very expensive. Potential concern with enhancing migration of possible DNAPL as the matrix is heated. May have to heat first from below the possible DNAPL zone ("hot floor" method - not readily applicable to bedrock).
Steam Flushing	Contact with contaminants not likely to be complete in fractured bedrock.
In-Situ Oxidation	Injection of oxidizing chemicals such as hydrogen peroxide or potassium permanganate. Difficult to inject the chemicals into the bedrock fractures where possible DNAPL exists.
In-Situ Reduction	Injection of reducing chemicals such as a slurry of zero-valent iron. Difficult to locate and inject the chemicals into the bedrock fractures where possible DNAPL exists.
Dual-Phase Extraction	Application of a high vacuum to deep wells to extract mobile DNAPL, contaminated groundwater, and vapors. If it is possible to dewater the formation, soil vapor extraction can be performed. Even if possible to implement this technology, it will still leave a mass of possible DNAPL.
Enhanced Reductive Dechlorination	Injection of vegetable oil or other electron donor to stimulate reductive dechlorination. Difficult to locate and inject the chemicals into the bedrock fractures where possible DNAPL exists.

Generated by: Daniel Brown Checked by: Jessica High

Appendix B: Petition Summary and Background Information

On March 16, 2011, McGuireWoods, on behalf of Rhodia Inc., filed a petition for rulemaking to the Division of Water Quality Director (DWQ), Coleen Sullins. The petition requests an amendment of the groundwater quality standard for 1,1-dichloroethylene (1,1-DCE) contained in 15A NCAC 2L .0202(g)(59) from 7 ug/L to 350 ug/L.

By regulation, groundwater standards are established as the lower of the six criteria contained in 15A NCAC 2L .0202(d) (1) – (6). Based on these criteria, the current standard for 1,1-DCE is the maximum contaminant level (MCL) of 7 ug/L. MCLs are federal drinking water standards established by the USEPA Office of Water and are applicable to public water supply systems regulated under the Federal Safe Drinking Water Act.

The petitioner seeks to amend the groundwater standard because the federal MCL for 1,1-DCE was calculated using outdated health effects data. The DWQ and the USEPA acknowledge that updated health effects data support calculation of a less stringent MCL. However, EPA does not plan to update the MCL because any potential revision is not likely to provide a meaningful opportunity for cost-savings or health risk reduction to public water systems and their customers. A revised standard of 350 ug/L would reduce cleanup costs for Rhodia and other sites.

The petitioner provided a legal opinion that 15A NCAC 2L .0202(d) and (e), in tandem, are sufficiently broad to establish the groundwater standard at 350 ug/L under 2L .0202(d)(1), based on the current toxicity data published in the USEPA's Integrated Risk Information System (IRIS) database, rather than the federal MCL, which was calculated prior to the updated toxicity data being published.

The 1,1-DCE standard issue was first brought forth by Rhodia and others during the Groundwater Triennial Review (GWTR) that ended in 2005 and again during the GWTR that ended in 2010. Both times the Environmental Management Committee (EMC) approved a 1,1,DCE groundwater standard of 7 ug/L. After consultation with its legal counsel, Frank Crawley, the EMC determined that 2L .0202(d) and (e) were not sufficiently broad to allow a change to the 1,1-DCE standard from 7 ug/L to 350 ug/L as requested.

In May 2005, the EMC Groundwater Committee (GWC) directed the DWQ to establish a Groundwater Stakeholder Group (GWSG) to discuss ways to amend the groundwater rules to ensure the use of the most recent toxicity information when developing groundwater standards. The GWSG consisted of representatives from various stakeholder groups, such as, Department of Environment and Natural Resources (DENR) regulatory agencies, city and county governments, major industries, environmental groups, agricultural interests, and public health. After much discussion, the GWSG could not reach consensus on how to amend the groundwater regulations and ultimately, the DWQ recommended to the GWC that the issue be dealt with by the variance process in 2L .0113. At its July 12, 2006 meeting, the GWC unanimously accepted and concurred with the DWQ recommendation that in individual site-specific cases, a variance under 2L .0113 could be approved that would allow less restrictive Groundwater Quality Standards while providing the site specific requirements necessary to protect public water supplies.

In November 2010, Rhodia submitted a site-specific variance request for a 1,1-DCE standard of 350 ug/L. The Division of Waste Management (DWM) , the regulatory authority over the site, reviewed the request and determined it to be incomplete based on the requirements in 2L .0113. Rhodia withdrew the variance request, stating that the variance approach was not an appropriate mechanism for seeking relief from a standard that was not based on current health effects information. Subsequently, Rhodia submitted the rulemaking petition.

At its May 2011 meeting, the GWC heard presentations on the rulemaking petition from the petitioner and DWQ staff. DWQ staff recommended that the petition be denied and that Rhodia work with DWM staff to address the deficiencies identified in their variance request.

After discussion, the GWC passed a motion to recommend that the full EMC proceed with rulemaking as proposed by the petitioner to amend the 1,1-DCE standard from 7 ug/L to 350 ug/L. The Committee acknowledged that, according to legal counsel, rule language is needed to allow deviation from 2L .0202(d), which requires that the groundwater standard be established at the lowest of the six criteria.

On July 14, 2011, the EMC approved Rhodia's Rulemaking Petition and directed the DWQ to initiate rulemaking to amend the groundwater standard for 1,1-DCE from 7 ug/L to 350 ug/L.

15A NCAC 02L .0202 is proposed for amendment as follows: (Rhodia Option 1)

15A NCAC 02L .0202 GROUNDWATER QUALITY STANDARDS

(a) The groundwater quality standards for the protection of the groundwaters of the state are those specified in this Rule. They are the maximum allowable concentrations resulting from any discharge of contaminants to the land or waters of the state, which may be tolerated without creating a threat to human health or which would otherwise render the groundwater unsuitable for its intended best usage.

(b) The groundwater quality standards for contaminants specified in Paragraphs (g) and (h) of this Rule are as listed, except that:

(1) Where the standard for a substance is less than the practical quantitation limit, the detection of that substance at or above the practical quantitation limit constitutes a violation of the standard.

(2) Where two or more substances exist in combination, the Director shall consider the effects of chemical interactions as determined by the Division of Public Health and may establish maximum concentrations at values less than those established in accordance with Paragraphs (c), (g), or (h) of this Rule. In the absence of information to the contrary, in accordance with Paragraph (d) of this Rule, the carcinogenic risks associated with carcinogens present shall be considered additive and the toxic effects associated with non-carcinogens present shall also be considered additive.

(3) Where naturally occurring substances exceed the established standard, the standard shall be the naturally occurring concentration as determined by the Director.

(c) Except for tracers used in concentrations which have been determined by the Division of Public Health to be protective of human health, and the use of which has been permitted by the Division, substances which are not naturally occurring and for which no standard is specified shall not be permitted in concentrations at or above the practical quantitation limit in Class GA or Class GSA groundwaters. Any person may petition the Director to establish an interim maximum allowable concentration for a substance for which a standard has not been established under this Rule. The petitioner shall submit relevant toxicological and epidemiological data, study results, and calculations necessary to establish a standard in accordance with Paragraph (d) of this Rule. Within three months after the establishment of an interim maximum allowable concentration for a substance by the Director, the Director shall initiate action to consider adoption of a standard for that substance.

(d) Groundwater quality standards for substances in Class GA and Class GSA groundwaters are established as the least of:

(1) Systemic threshold concentration calculated as follows: [Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)];

(2) Concentration which corresponds to an incremental lifetime cancer risk of 1x10-6;

(3) Taste threshold limit value;

(4) Odor threshold limit value;

(5) Maximum contaminant level; or

(6) National secondary drinking water standard.

(e) The following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in Paragraph (d) of this Rule.

(1) Integrated Risk Information System (U.S. EPA).

(2) Health Advisories (U.S. EPA Office of Drinking Water).

(3) Other health risk assessment data published by U.S. EPA.

(4) Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.

(f) Groundwater quality standards specified in Paragraphs (g) and (h) of this Rule and interim maximum allowable concentrations established pursuant to Paragraph (c) of this Rule shall be reviewed on a triennial basis. Appropriate modifications to established standards shall be made in accordance with the procedure prescribed in Paragraph (d) of this Rule where modifications are considered appropriate based on data published subsequent to the previous review.

(g) Class GA Standards. Where not otherwise indicated, the standard refers to the total concentration in micrograms per liter of any constituent in a dissolved, colloidal or particulate form which is mobile in groundwater. This does not apply to sediment or other particulate matter which is preserved in a groundwater sample as a result of well construction or sampling procedures. The Class GA standards are:

(1) Acenaphthene: 80;

(2) Acenaphthylene: 200;

(3) Acetone: 6 mg/L;
(4) Acrylamide: 0.008;
(5) Anthracene: 2 mg/L;
(6) Arsenic: 10;
(7) Atrazine and chlorotriazine metabolites: 3;
(8) Barium: 700;
(9) Benzene: 1;
(10) Benzo(a)anthracene (benz(a)anthracene): 0.05;
(11) Benzo(b)fluoranthene: 0.05;
(12) Benzo(k)fluoranthene: 0.5;
(13) Benzoic acid: 30 mg/L;
(14) Benzo(g,h,i,)perylene: 200;
(15) Benzo(a)pyrene: 0.005;
(16) Bis(chloroethyl)ether: 0.03;
(17) Bis(2-ethylhexyl) phthalate (di(2-ethylhexyl) phthalate): 3;
(18) Boron: 700;
(19) Bromodichloromethane: 0.6;
(20) Bromoform (tribromomethane): 4;
(21) n-Butylbenzene: 70;
(22) sec-Butylbenzene: 70;
(23) tert-Butylbenzene: 70;
(24) Butylbenzyl phthalate: 1 mg/L;
(25) Cadmium: 2;
(26) Caprolactam: 4 mg/L;
(27) Carbofuran: 40;
(28) Carbon disulfide: 700;
(29) Carbon tetrachloride: 0.3;
(30) Chlordane: 0.1;
(31) Chloride: 250 mg/L;
(32) Chlorobenzene: 50;
(33) Chloroethane: 3,000;
(34) Chloroform (trichloromethane): 70;
(35) Chloromethane (methyl chloride): 3;
(36) 2-Chlorophenol: 0.4;
(37) 2-Chlorotoluene (o-chlorotoluene): 100;
(38) Chromium: 10;
(39) Chrysene: 5;
(40) Coliform organisms (total): 1 per 100 milliliters;
(41) Color: 15 color units;
(42) Copper: 1 mg/L;
(43) Cyanide (free cyanide): 70;
(44) 2, 4-D (2,4-dichlorophenoxy acetic acid): 70;
(45) DDD: 0.1;
(46) DDT: 0.1;
(47) Dibenz(a,h)anthracene: 0.005;
(48) Dibromochloromethane: 0.4;
(49) 1,2-Dibromo-3-chloropropane: 0.04;
(50) Dibutyl (or di-n-butyl) phthalate: 700;
(51) 1,2-Dichlorobenzene (orthodichlorobenzene): 20;
(52) 1,3-Dichlorobenzene (metadichlorobenzene): 200;
(53) 1,4-Dichlorobenzene (paradichlorobenzene): 6;
(54) Dichlorodifluoromethane (Freon-12; Halon): 1 mg/L;
(55) 1,1-Dichloroethane: 6;
(56) 1,2-Dichloroethane (ethylene dichloride): 0.4;
(57) 1,2-Dichloroethene (cis): 70;

(58) 1,2-Dichloroethene (trans): 100;

(59) 1,1-Dichloroethylene (vinylidene chloride): ~~7~~350;

(60) 1,2-Dichloropropane: 0.6;

(61) 1,3-Dichloropropene (cis and trans isomers): 0.4;

(62) Dieldrin: 0.002;

(63) Diethylphthalate: 6 mg/L;

(64) 2,4-Dimethylphenol (m-xylenol): 100;

(65) Di-n-octyl phthalate: 100;

(66) 1,4-Dioxane (p-dioxane): 3;

(67) Dioxin (2,3,7,8-TCDD): 0.0002 ng/L;

(68) 1,1– Diphenyl (1,1,-biphenyl): 400;

(69) Dissolved solids (total): 500 mg/L;

(70) Disulfoton: 0.3;

(71) Diundecyl phthalate (Santicizer 711): 100;

(72) Endosulfan: 40;

(73) Endrin, total: (includes endrin, endrin aldehyde and endrin ketone): 2;

(74) Epichlorohydrin: 4;

(75) Ethyl acetate: 3 mg/L;

(76) Ethylbenzene: 600;

(77) Ethylene dibromide (1,2-dibromoethane): 0.02;

(78) Ethylene glycol: 10 mg/L;

(79) Fluoranthene: 300;

(80) Fluorene: 300;

(81) Fluoride: 2 mg/L;

(82) Foaming agents: 500;

(83) Formaldehyde: 600;

(84) Gross alpha (adjusted) particle activity (excluding radium-226 and uranium): 15 pCi/L;

(85) Heptachlor: 0.008;

(86) Heptachlor epoxide: 0.004;

(87) Heptane: 400;

(88) Hexachlorobenzene (perchlorobenzene): 0.02;

(89) Hexachlorobutadiene: 0.4;

(90) Hexachlorocyclohexane isomers (technical grade): 0.02;

(91) n-Hexane: 400;

(92) Indeno(1,2,3-cd)pyrene: 0.05;

(93) Iron: 300;

(94) Isophorone: 40;

(95) Isopropylbenzene: 70;

(96) Isopropyl ether: 70;

(97) Lead: 15;

(98) Lindane (gamma hexachlorocyclohexane): 0.03;

(99) Manganese: 50;

(100) Mercury: 1;

(101) Methanol: 4 mg/L;

(102) Methoxychlor: 40;

(103) Methylene chloride (dichloromethane): 5;

(104) Methyl ethyl ketone (2-butanone): 4 mg/L;

(105) 2-Methylnaphthalene: 30;

(106) 3-Methylphenol (m-cresol): 400;

(107) 4-Methylphenol (p-cresol): 40;

(108) Methyl tert-butyl ether (MTBE): 20;

(109) Naphthalene: 6;

(110) Nickel: 100;

(111) Nitrate: (as N) 10 mg/L;

(112) Nitrite: (as N) 1 mg/L;

(113) N-nitrosodimethylamine: 0.0007;
(114) Oxamyl: 200;
(115) Pentachlorophenol: 0.3;
(116) Petroleum aliphatic carbon fraction class (C5 - C8): 400;
(117) Petroleum aliphatic carbon fraction class (C9 - C18): 700;
(118) Petroleum aliphatic carbon fraction class (C19 - C36): 10 mg/L;
(119) Petroleum aromatics carbon fraction class (C9 - C22): 200;
(120) pH: 6.5 - 8.5;
(121) Phenanthrene: 200;
(122) Phenol: 30;
(123) Phorate: 1;
(124) n-Propylbenzene: 70;
(125) Pyrene: 200;
(126) Selenium: 20;
(127) Silver: 20;
(128) Simazine: 4;
(129) Styrene: 70;
(130) Sulfate: 250 mg/L;
(131) 1,1,2,2-Tetrachloroethane: 0.2;
(132) Tetrachloroethylene (perchloroethylene; PCE): 0.7;
(133) 2,3,4,6-Tetrachlorophenol: 200;
(134) Toluene: 600;
(135) Toxaphene: 0.03;
(136) 2, 4, 5,-TP (Silvex): 50;
(137) 1,2,4-Trichlorobenzene: 70;
(138) 1,1,1-Trichloroethane: 200;
(139) Trichloroethylene (TCE): 3;
(140) Trichlorofluoromethane: 2 mg/L;
(141) 1,2,3-Trichloropropane: 0.005;
(142) 1,2,4-Trimethylbenzene: 400;
(143) 1,3,5-Trimethylbenzene: 400;
(144) 1,1,2-Trichloro-1,2,2-trifluoroethane (CFC-113): 200 mg/L;
(145) Vinyl chloride: 0.03;
(146) Xylenes (o-, m-, and p-): 500; and
(147) Zinc: 1 mg/L.

(h) Class GSA Standards. The standards for this class are the same as those for Class GA except as follows:
(1) chloride: allowable increase not to exceed 100 percent of the natural quality concentration; and
(2) total dissolved solids: 1000 mg/l.

(i) Class GC Waters.
(1) The concentrations of substances which, at the time of classification, exceed the standards applicable to Class GA or GSA groundwaters shall not be caused to increase, nor shall the concentrations of other substances be caused to exceed the GA or GSA standards as a result of further disposal of contaminants to or beneath the surface of the land within the boundary of the area classified GC.
(2) The concentrations of substances which, at the time of classification, exceed the standards applicable to GA or GSA groundwaters shall not be caused to migrate as a result of activities within the boundary of the GC classification, so as to violate the groundwater or surface water quality standards in adjoining waters of a different class.
(3) Concentrations of specific substances, which exceed the established standard at the time of classification, are listed in Section .0300 of this Subchapter.

History Note: *Authority G.S. 143-214.1; 143B-282(a)(2);*
Eff. June 10, 1979;
Amended Eff. November 1, 1994; October 1, 1993; September 1, 1992; August 1, 1989;
Temporary Amendment Eff. June 30, 2002;
Amended Eff. August 1, 2002;

Temporary Amendment Expired February 9, 2003;
Amended Eff. July 2012; January 1, 2010; April 1, 2005.

15A NCAC 02L .0202 is proposed for amendment as follows: (DWQ Option 2)

15A NCAC 02L .0202 GROUNDWATER QUALITY STANDARDS

(a) The groundwater quality standards for the protection of the groundwaters of the state are those specified in this Rule. They are the maximum allowable concentrations resulting from any discharge of contaminants to the land or waters of the state, which may be tolerated without creating a threat to human health or which would otherwise render the groundwater unsuitable for its intended best usage.

(b) The groundwater quality standards for contaminants specified in Paragraphs (g) and (h) of this Rule are as listed, except that:

(1) Where the standard for a substance is less than the practical quantitation limit, the detection of that substance at or above the practical quantitation limit constitutes a violation of the standard.

(2) Where two or more substances exist in combination, the Director shall consider the effects of chemical interactions as determined by the Division of Public Health and may establish maximum concentrations at values less than those established in accordance with Paragraphs (c), (g), or (h) of this Rule. In the absence of information to the contrary, in accordance with Paragraph (d) of this Rule, the carcinogenic risks associated with carcinogens present shall be considered additive and the toxic effects associated with non-carcinogens present shall also be considered additive.

(3) Where naturally occurring substances exceed the established standard, the standard shall be the naturally occurring concentration as determined by the Director.

(c) Except for tracers used in concentrations which have been determined by the Division of Public Health to be protective of human health, and the use of which has been permitted by the Division, substances which are not naturally occurring and for which no standard is specified shall not be permitted in concentrations at or above the practical quantitation limit in Class GA or Class GSA groundwaters. Any person may petition the Director to establish an interim maximum allowable concentration for a substance for which a standard has not been established under this Rule. The petitioner shall submit relevant toxicological and epidemiological data, study results, and calculations necessary to establish a standard in accordance with Paragraph (d) of this Rule. Within three months after the establishment of an interim maximum allowable concentration for a substance by the Director, the Director shall initiate action to consider adoption of a standard for that substance.

(d) Except as provided in Paragraph (f), groundwater ~~Groundwater~~ quality standards for substances in Class GA and Class GSA groundwaters are established as the least of:

(1) Systemic threshold concentration calculated as follows: [Reference Dose (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (.10 for inorganics; .20 for organics)] / [2 liters/day (avg. water consumption)];

(2) Concentration which corresponds to an incremental lifetime cancer risk of 1x10-6;

(3) Taste threshold limit value;

(4) Odor threshold limit value;

(5) Maximum contaminant level; or

(6) National secondary drinking water standard.

(e) The following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in Paragraph (d) of this Rule.

(1) Integrated Risk Information System (U.S. EPA).

(2) Health Advisories (U.S. EPA Office of Drinking Water).

(3) Other health risk assessment data published by U.S. EPA.

(4) Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.

(f) The Commission may establish groundwater standards less stringent than existing maximum contaminant levels or national secondary drinking water standards if it finds, after public notice and opportunity for hearing, that

(1) more recent data published in any of the EPA health references listed in paragraph (e) results in a standard which is protective of public health, taste threshold, or odor threshold,

(2) such a standard will not endanger the public health and safety, including health and environmental effects from exposure to groundwater contaminants, and

(3) compliance with a standard based on the maximum contaminant level or national secondary drinking water standard would produce serious hardship without equal or greater public benefit.

~~(f)~~(g) Groundwater quality standards specified in Paragraphs ~~(g)~~(h) and ~~(h)~~(i) of this Rule and interim maximum allowable concentrations established pursuant to Paragraph (c) of this Rule shall be reviewed on a triennial basis. Appropriate modifications to established standards shall be made in accordance with the procedure prescribed in Paragraph (d) of this Rule where modifications are considered appropriate based on data published subsequent to the previous review.

~~(g)~~(h) Class GA Standards. Where not otherwise indicated, the standard refers to the total concentration in micrograms per liter of any constituent in a dissolved, colloidal or particulate form which is mobile in groundwater. This does not apply to sediment or other particulate matter which is preserved in a groundwater sample as a result of well construction or sampling procedures. The Class GA standards are:

(1) Acenaphthene: 80;
(2) Acenaphthylene: 200;
(3) Acetone: 6 mg/L;
(4) Acrylamide: 0.008;
(5) Anthracene: 2 mg/L;
(6) Arsenic: 10;
(7) Atrazine and chlorotriazine metabolites: 3;
(8) Barium: 700;
(9) Benzene: 1;
(10) Benzo(a)anthracene (benz(a)anthracene): 0.05;
(11) Benzo(b)fluoranthene: 0.05;
(12) Benzo(k)fluoranthene: 0.5;
(13) Benzoic acid: 30 mg/L;
(14) Benzo(g,h,i,)perylene: 200;
(15) Benzo(a)pyrene: 0.005;
(16) Bis(chloroethyl)ether: 0.03;
(17) Bis(2-ethylhexyl) phthalate (di(2-ethylhexyl) phthalate): 3;
(18) Boron: 700;
(19) Bromodichloromethane: 0.6;
(20) Bromoform (tribromomethane): 4;
(21) n-Butylbenzene: 70;
(22) sec-Butylbenzene: 70;
(23) tert-Butylbenzene: 70;
(24) Butylbenzyl phthalate: 1 mg/L;
(25) Cadmium: 2;
(26) Caprolactam: 4 mg/L;
(27) Carbofuran: 40;
(28) Carbon disulfide: 700;
(29) Carbon tetrachloride: 0.3;
(30) Chlordane: 0.1;
(31) Chloride: 250 mg/L;
(32) Chlorobenzene: 50;
(33) Chloroethane: 3,000;
(34) Chloroform (trichloromethane): 70;
(35) Chloromethane (methyl chloride): 3;
(36) 2-Chlorophenol: 0.4;
(37) 2-Chlorotoluene (o-chlorotoluene): 100;
(38) Chromium: 10;
(39) Chrysene: 5;
(40) Coliform organisms (total): 1 per 100 milliliters;
(41) Color: 15 color units;
(42) Copper: 1 mg/L;
(43) Cyanide (free cyanide): 70;
(44) 2, 4-D (2,4-dichlorophenoxy acetic acid): 70;
(45) DDD: 0.1;
(46) DDT: 0.1;

(47) Dibenz(a,h)anthracene: 0.005;
(48) Dibromochloromethane: 0.4;
(49) 1,2-Dibromo-3-chloropropane: 0.04;
(50) Dibutyl (or di-n-butyl) phthalate: 700;
(51) 1,2-Dichlorobenzene (orthodichlorobenzene): 20;
(52) 1,3-Dichlorobenzene (metadichlorobenzene): 200;
(53) 1,4-Dichlorobenzene (paradichlorobenzene): 6;
(54) Dichlorodifluoromethane (Freon-12; Halon): 1 mg/L;
(55) 1,1-Dichloroethane: 6;
(56) 1,2-Dichloroethane (ethylene dichloride): 0.4;
(57) 1,2-Dichloroethene (cis): 70;
(58) 1,2-Dichloroethene (trans): 100;
(59) 1,1-Dichloroethylene (vinylidene chloride): 7;
(60) 1,2-Dichloropropane: 0.6;
(61) 1,3-Dichloropropene (cis and trans isomers): 0.4;
(62) Dieldrin: 0.002;
(63) Diethylphthalate: 6 mg/L;
(64) 2,4-Dimethylphenol (m-xylenol): 100;
(65) Di-n-octyl phthalate: 100;
(66) 1,4-Dioxane (p-dioxane): 3;
(67) Dioxin (2,3,7,8-TCDD): 0.0002 ng/L;
(68) 1,1– Diphenyl (1,1,-biphenyl): 400;
(69) Dissolved solids (total): 500 mg/L;
(70) Disulfoton: 0.3;
(71) Diundecyl phthalate (Santicizer 711): 100;
(72) Endosulfan: 40;
(73) Endrin, total: (includes endrin, endrin aldehyde and endrin ketone): 2;
(74) Epichlorohydrin: 4;
(75) Ethyl acetate: 3 mg/L;
(76) Ethylbenzene: 600;
(77) Ethylene dibromide (1,2-dibromoethane): 0.02;
(78) Ethylene glycol: 10 mg/L;
(79) Fluoranthene: 300;
(80) Fluorene: 300;
(81) Fluoride: 2 mg/L;
(82) Foaming agents: 500;
(83) Formaldehyde: 600;
(84) Gross alpha (adjusted) particle activity (excluding radium-226 and uranium): 15 pCi/L;
(85) Heptachlor: 0.008;
(86) Heptachlor epoxide: 0.004;
(87) Heptane: 400;
(88) Hexachlorobenzene (perchlorobenzene): 0.02;
(89) Hexachlorobutadiene: 0.4;
(90) Hexachlorocyclohexane isomers (technical grade): 0.02;
(91) n-Hexane: 400;
(92) Indeno(1,2,3-cd)pyrene: 0.05;
(93) Iron: 300;
(94) Isophorone: 40;
(95) Isopropylbenzene: 70;
(96) Isopropyl ether: 70;
(97) Lead: 15;
(98) Lindane (gamma hexachlorocyclohexane): 0.03;
(99) Manganese: 50;
(100) Mercury: 1;
(101) Methanol: 4 mg/L;

(102) Methoxychlor: 40;
(103) Methylene chloride (dichloromethane): 5;
(104) Methyl ethyl ketone (2-butanone): 4 mg/L;
(105) 2-Methylnaphthalene: 30;
(106) 3-Methylphenol (m-cresol): 400;
(107) 4-Methylphenol (p-cresol): 40;
(108) Methyl tert-butyl ether (MTBE): 20;
(109) Naphthalene: 6;
(110) Nickel: 100;
(111) Nitrate: (as N) 10 mg/L;
(112) Nitrite: (as N) 1 mg/L;
(113) N-nitrosodimethylamine: 0.0007;
(114) Oxamyl: 200;
(115) Pentachlorophenol: 0.3;
(116) Petroleum aliphatic carbon fraction class (C5 - C8): 400;
(117) Petroleum aliphatic carbon fraction class (C9 - C18): 700;
(118) Petroleum aliphatic carbon fraction class (C19 - C36): 10 mg/L;
(119) Petroleum aromatics carbon fraction class (C9 - C22): 200;
(120) pH: 6.5 - 8.5;
(121) Phenanthrene: 200;
(122) Phenol: 30;
(123) Phorate: 1;
(124) n-Propylbenzene: 70;
(125) Pyrene: 200;
(126) Selenium: 20;
(127) Silver: 20;
(128) Simazine: 4;
(129) Styrene: 70;
(130) Sulfate: 250 mg/L;
(131) 1,1,2,2-Tetrachloroethane: 0.2;
(132) Tetrachloroethylene (perchloroethylene; PCE): 0.7;
(133) 2,3,4,6-Tetrachlorophenol: 200;
(134) Toluene: 600;
(135) Toxaphene: 0.03;
(136) 2, 4, 5,-TP (Silvex): 50;
(137) 1,2,4-Trichlorobenzene: 70;
(138) 1,1,1-Trichloroethane: 200;
(139) Trichloroethylene (TCE): 3;
(140) Trichlorofluoromethane: 2 mg/L;
(141) 1,2,3-Trichloropropane: 0.005;
(142) 1,2,4-Trimethylbenzene: 400;
(143) 1,3,5-Trimethylbenzene: 400;
(144) 1,1,2-Trichloro-1,2,2-trifluoroethane (CFC-113): 200 mg/L;
(145) Vinyl chloride: 0.03;
(146) Xylenes (o-, m-, and p-): 500; and
(147) Zinc: 1 mg/L.

~~(h)~~(i) Class GSA Standards. The standards for this class are the same as those for Class GA except as follows:
(1) chloride: allowable increase not to exceed 100 percent of the natural quality concentration; and
(2) total dissolved solids: 1000 mg/l.

~~(i)~~(j) Class GC Waters.
(1) The concentrations of substances which, at the time of classification, exceed the standards applicable to Class GA or GSA groundwaters shall not be caused to increase, nor shall the concentrations of other substances be caused to exceed the GA or GSA standards as a result of further disposal of contaminants to or beneath the surface of the land within the boundary of the area classified GC.

(2) The concentrations of substances which, at the time of classification, exceed the standards applicable to GA or GSA groundwaters shall not be caused to migrate as a result of activities within the boundary of the GC classification, so as to violate the groundwater or surface water quality standards in adjoining waters of a different class.

(3) Concentrations of specific substances, which exceed the established standard at the time of classification, are listed in Section .0300 of this Subchapter.

History Note: *Authority G.S. 143-214.1; 143B-282(a)(2);*
Eff. June 10, 1979;
Amended Eff. November 1, 1994; October 1, 1993; September 1, 1992; August 1, 1989;
Temporary Amendment Eff. June 30, 2002;
Amended Eff. August 1, 2002;
Temporary Amendment Expired February 9, 2003;
Amended Eff. <u>July 1, 2012;</u> January 1, 2010; April 1, 2005.

15A NCAC 02L .0113 is proposed for amendment as follows: (DWQ Option 3)

15A NCAC 02L .0113 VARIANCE

(a) The Commission, on its own initiative or pursuant to a request under G.S. 143-215.3(e), may grant variances to the rules of this Subchapter.

(b) Requests for variances are filed by letter from the applicant to the Environmental Management Commission. The application shall be mailed to the chairman of the Commission in care of the Director, Division of ~~Environmental Management, Post Office Box 29535, Raleigh, N.C. 27626-0535.~~ Water Quality, 1617 Mail Service Center, Raleigh, N.C. 27699-1617.

(c) For site-specific variances, the ~~The~~ application shall contain the following information:

(1) Applications filed by counties or municipalities must include a resolution of the County Board of Commissioners or the governing board of the municipality requesting the variance.

(2) A description of the past, existing or proposed activities or operations that have or would result in a discharge of contaminants to the groundwaters.

(3) Description of the proposed area for which a variance is requested. A detailed location map, showing the orientation of the facility, potential for groundwater contaminant migration, as well as the area covered by the variance request, with reference to at least two geographic references (numbered roads, named streams/rivers, etc.) must be included.

(4) Supporting information to establish that the variance will not endanger the public health and safety, including health and environmental effects from exposure to groundwater contaminants. (Location of wells and other water supply sources including details of well construction within 1/2 mile of site must be shown on a map).

(5) Supporting information to establish that requirements of this Rule cannot be achieved by providing the best available technology economically reasonable. This information must identify specific technology considered, and the costs of implementing the technology and the impact of the costs on the applicant.

(6) Supporting information to establish that compliance would produce serious financial hardship on the applicant.

(7) Supporting information that compliance would produce serious financial hardship without equal or greater public benefit.

(8) A copy of any Special Order that was issued in connection with contaminants in the proposed area and supporting information that applicant has complied with the Special Order.

(9) A list of the names and addresses of any property owners within the proposed area of the variance as well as any property owners adjacent to the site covered by the variance.

(d) For state-wide variances to groundwater standards established in Section .0202, the application shall contain the following information:

(1) Supporting information to establish that the variance will not endanger the public health and safety, including health and environmental effects from exposure to groundwater at the proposed constituent levels. This should include information obtained from the following references.

(a) Integrated risk Information System (U.S. EPA).

(b) Health Advisories (U.S. EPA Office of Drinking Waters).

(c) Other health risk assessment data published by U.S. EPA.

(d) Other relevant, published health and ecological risk assessment data, and scientifically valid peer-reviewed published toxicological data.

(2) A list of all known potentially affected sites, to include permitted sites and incident sites. For each site listed, a map for each site with the location of wells and other water supply sources within ½ mile of the affected site must be provided.

(3) A list of increased costs for treatment for any of the wells or water supply sources listed in Paragraph (2) above due to the proposed variance to Section .0202.

~~(d)~~(e) Upon receipt of the application, the Director will review it for completeness and request additional information if necessary. When the application is complete, the Director shall give public notice of the application and schedule the matter for a public hearing in accordance with G.S. 143-215.4(b) and the procedures set out in Paragraph ~~(e)~~(f) of this Rule.

~~(e)~~(f) Notice of Public Hearing:

(1) Notice of public hearing on any variance application shall be circulated in the geographical areas of the proposed variance by the Director at least 30 days prior to the date of the hearing:

(A) by publishing the notice one time in a newspaper having general circulation in said county;

(B) by mailing to the North Carolina Department of Environment, Health, and Natural Resources, Division of Environmental Health and appropriate local health agency;
(C) by mailing to any other federal, state or local agency upon request;
(D) by mailing to the local governmental unit or units having jurisdiction over the geographic area covered by the variance;
(E) by mailing to any property owner within the proposed area of the variance, as well as any property owners adjacent to the site covered by the variance; and
(F) by mailing to any person or group upon request.

(2) The contents of public notice of any hearing shall include at least the following:
(A) name, address, and phone number of agency holding the public hearing;
(B) name and address of each applicant whose application will be considered at the meeting;
(C) brief summary of the variance request;
(D) geographic description of a proposed area for which a variance is requested;
(E) brief description of activities or operations which have or will result in the discharge of contaminants to the groundwaters described in the variance application;
(F) a brief reference to the public notice issued for each variance application;
(G) information regarding the time and location for the hearing;
(H) the purpose of the hearing;
(I) address and phone number of premises at which interested persons may obtain further information, request a copy of each application, and inspect and copy forms and related documents; and
(J) a brief description of the nature of the hearing including the rules and procedures to be followed. The notice shall also state that additional information is on file with the Director and may be inspected at any time during normal working hours. Copies of the information on file will be made available upon request and payment of cost or reproduction.

~~(f)~~(g) All comments received within 30 days following the date of the public hearing shall be made part of the application file and shall be considered by the Commission prior to taking final action on the application.

~~(g)~~(h) In determining whether to grant a variance, the Commission shall consider whether the applicant has complied with any Special Order, or Special Order by Consent issued under G.S. 143-215.2.

~~(h)~~(i) ~~If the Commission's final decision is unacceptable, the applicant may file~~ The applicant may appeal the Commission's final decision by filing a petition for a contested case in accordance with Chapter 150B of the General Statutes. If the petition is not filed within 60 days, the Commission's decision on the variance shall be final and binding.

~~(i) A variance shall not operate as a defense to an action at law based upon a public or private nuisance theory or any other cause of action.~~

History Note: Authority G.S. 143-215.3(a)(1); 143-215.3(a)(3); 143-215.3(a)(4); 143-215.3(e); 143-215.4;
Eff. August 1, 1989;
Amended Eff. July 1, 2012; October 1, 1993.

Appendix F: Summary of Proposed Rule Changes

Rule Citation	Proposed Revision	Potential Economic Impact
15A NCAC 02L .0202(g)(59) *(Rhodia Option 1)*	(g)(59) Amends the 1,1-dichloroethylene groundwater standard from 7 ug/L to 350 ug/L.	-Compliance cost savings for facilities with releases of 1,1-dichloroethylene (1,1-DCE). -Compliance cost savings to permitted facilities (for example, non-discharge, pretreatment, landfills). -Compliance cost to public water supply systems using 1,1-DCE-contaminated groundwater above the federal maximum contaminant level (MCL) of 7 ug/L.
15A NCAC 02L .0202(d) & (f) *(DWQ Option 2)*	(d) Allows an exception to the criteria for establishing groundwater standards. (f) Allows the Environmental Management Commission to establish groundwater standards less stringent than existing Maximum Contaminant Levels and secondary drinking water standards under certain circumstances.	-Compliance cost savings for facilities with releases of 1,1-dichloroethylene (1,1-DCE). -Compliance cost savings to permitted facilities (for example, non-discharge, pretreatment, landfills). -Compliance cost to public water supply systems using 1,1-DCE-contaminated groundwater above the federal maximum contaminant level (MCL) of 7 ug/L.
15A NCAC 02L .0113 (b) – (i) *(DWQ Option 3)*	(b) Updates the Division of Water Quality mailing address. (d) Adds a state-wide variance option and application requirements. Note: original paragraphs (d)-(i) are re-alphabetized (e)-(i). (h) & (i) adds and deletes text for clarity.	-No cost or cost savings expected.

RADIATOR SPECIALTY COMPANY

600 Radiator Road, Indian Trail, NC 28079-5225

VIA OVERNIGHT AND ELECTRONIC MAIL

Environmental Management Commission
c/o Lois Thomas, EMC Recording Clerk
Director's Office
Division of Water Quality
512 North Salisbury Street
Raleigh, North Carolina 27604

Re: Letter of Support for Rhodia Inc.'s Petition for Rulemaking to Change Groundwater Quality Standard for 1,1-Dichloroethylene (1,1-DCE)

Dear Members of the Environmental Management Commission:

Radiator Specialty Company is writing this letter to express its support of Rhodia Inc.'s rulemaking petition to change the groundwater quality standard for 1,1-DCE to 350 μg/L.

Radiator Specialty has been headquartered in North Carolina since its founding in 1924. Today, from its corporate headquarters and 400,000 square foot manufacturing plant in Indian Trail, Radiator Specialty develops, manufactures and markets high performance products for auto, motorcycle, plumbing, hardware and industrial applications for more than 1,600 customers in 81 countries. Radiator Specialty is committed to conducting all of its operations in an environmentally responsible manner.

Just as the State expects us to operate in compliance with environmental laws and regulations, Radiator Specialty expects the State to do so as well. During the 2008 Triennial Review, we along with Rhodia Inc. and Ashland Inc. submitted a written public comment that the groundwater quality standard for 1,1-DCE should be changed to 350 μg/L. The basis for that request was the same as the basis for Rhodia's rulemaking petition. Radiator Specialty believes that North Carolina's regulations require that this change be made and we ask you to approve Rhodia's petition at your July 14 meeting.

We would request that a copy of this letter be provided to each member of the EMC and that it also be placed on the EMC's website as part of the materials related to the Rhodia petition.

Sincerely,

Stuart A. Kerkhoff

Stuart A. Kerkhoff
Environmental Manager
Radiator Specialty Company

From: David L. Duncklee [dave@dunckleedunham.com]
Sent: Thursday, July 07, 2011 9:15 AM
To: Thomas, Lois
Cc: 'Daphne Jones'; tdunham@duncldeedunham.com
Subject: Support for EMC's Proposed Rulemaking re: 1,1-DCE

Dear Ms. Thomas,

I am President of Duncklee & Dunham, P.C., a Geological and Engineering Environmental Consulting firm located in Cary, North Carolina. I understand the July 14, 2011 EMC meeting will have an agenda item relating to considering establishing a new groundwater standard for 1,1-dichloroethene (1,1-DCE) at 350 □g/L, up from the current level of 7 □g/L. I have been following this case with interest, as it makes sense that North Carolina groundwater quality standards are based on the most current scientific and toxicological data available.

I understand the current 1,1-DCE level of 7 □g/L is based on the lowest of the standards the Division of Water Quality considers for comparison, in this case the federal maximum concentration limit (MCL). I understand that the oral reference dose was changed for 1,1-DCE in 2003, but EPA did not change the MCL for this constituent, and has no plans to do so because of non-scientific reasons, e.g. competing workload priorities and administrative costs associated with the rulemaking. I do not believe it was the legislative intent for 2L standards to use the least value if that value was not calculated based on the most current toxicological information.

Even though the state□s toxicologist calculated the groundwater quality standard should be 350 □g/L in 2004 based on the updated reference dose information, I understand the Division of Water Quality refused to change the 1,1-DCE standards because of the way their own 2L rules were written. I am optimistic the EMC ruling will be based on logic, not adherence to a standard that no longer has the basis to be set at that level.

Duncklee & Dunham has had many clients affected by the changes/additions in groundwater standards and IMACs, often requiring much more money to be spent to clean up groundwater to meet these standards. It appears that the regulated community may have to bear considerable additional costs to meet a standard that has no scientific basis.

On behalf of the professional geological and engineering staff of Duncklee & Dunham, P.C. please consider this letter of support for the Rhodia Petition for the amendment of the current 1,1-DCE groundwater standard to be raised from 7□g/L to 350 □g/L.

Sincerely,

David L. Duncklee, PG, RSM
Senior Hydrogeologist
Mobile: 919-417-9923
Office: 919-858-9898 x201
dave@duncldeedunham.com

A Professional Geologic and Engineering Corporation

Appendix I: NCDENR Outreach via Email to Industry/ Private Sector

Manufacturers and Chemical Industry Council of North Carolina (MCIC)
Preston Howard, President
620 N. West Street, Suite 101
Raleigh, NC 27603
Telephone: 919-834-9459
E-Mail: preston.howard@mcicnc.org
jim.kuszaj jim@mcicnc.org
Web Site: http://www.mcicnc.org/index.html

Member Companies:

Air Products and Chemicals, Inc.	GlaxoSmithKline
Alcoa	Hexion
Archer Daniels Midland Co	International Paper
BASF Corporation	Invista
Blue Ridge Paper Products	Kao Specialties Americas LLC
Cargill	Kapstone Kraft Paper Corp.
Carolina Stalite	Kimberly Clark
Caterpillar, Inc	Lord Corporation
Celgard	MeadWestvaco
Chemtura	MOEN Incorporated
Ciba Specialty Chemicals	National Starch & Chemical Company
Clariant Corporation	Novozymes North America
Cognis	Oak-Bark Corp.
Corn Products International, Inc.	PCS Phosphate Company, Inc.
Corning Incorporated	Pressure Chemical Co.
Covidien/Mallinckrodt	RJ Reynolds Tobacco Company
DAK Americas	Resinall Corporation
Domtar Paper Company, LLC	Rohm & Haas
Dow Corning	Shurtape Technologies, Inc.
DuPont Company	Surry Chemicals, Inc.
Elementis Chromium	Syngenta Crop Protection
Evonik Stockhausen.	Trinity Manufacturing, Inc.
ExxonMobile Chemical	Unilin US MDF
FMC Corporation	Univar
Fortron Industries	Vertellus Performance Materials
General Electric	Weyerhaeuser Company
Georgia-PacificCorporation	

MCIC Business Partners
Arcadis
EI, Inc.
ENSR Consulting and Engineering (NC), Inc.
Hunton & Williams
Kilpartick Stockton LLP
McNair Law Firm, P.A.
Stearns & Wheler, PLLC
Trinity Consultants
URS Corporation - North Carolina
Womble, Carlyle, Sandridge & Rice, PLLC

North Carolina Chamber (formerly NC Citizens for Business & Industry)
S. Lewis Ebert, President and CEO
Raleigh Corporate Center
701 Corporate Center Drive, Suite 400
Raleigh, N.C. 27607
919-836-1407
info@ncchamber.net
lebert@ncchamber.net
Wesley Gappens, Communications Specialist
wgappens@ncchamber.net
919-836-1418
Web Site: http://www.ncchamber.net/mx/hm.asp?id=home

N.C. Rural Economic Development Center
Thomas W. Lambeth, Chairman
Billy Ray Hall, President
4021 Carya Drive, Raleigh, NC 27610
info@ncruralcenter.org
http://www.ncruralcenter.org/
Telephone: (919) 250-4314
Garnet Bass, Director of communications
gbass@ncruralcenter.org

Progress Energy Service Company, LLC
Mick Greeson
410 S. Wilmington Street
Raleigh, NC 27601
919-546-6129
mick.greeson@pgnmail.com
Web Site: https://www.progress-energy.com/

Duke Energy Corporation
George T. Everett, vice president,
Environmental and Public Policy
526 South Church Street
Charlotte, NC 28202
Everett, George T" GTEverett@duke-energy.com
Web Site: http://www.duke-energy.com/north-carolina.asp

Treated Wood Council, Inc.
Jeff Miller, Executive Director
1111 19th St., NW, Ste. 800
Washington, DC 20036
Phone: 202-463-2045
E-mail: jeff_miller@treated-wood.org
Web Site: http://www.treated-wood.org/home.html

North Carolina Pork Council
Tommy Stevens, Director of Environmental Services
tommy@ncpork.org
2300 Rexwoods Drive
Suite 340 Raleigh, NC 27607
Phone: 919-781-0361
Web Site: http://www.ncpork.org/index.jsp

NC Association of County Commissioners
David F. Thompson, Exec. Director
david.thompson@ncacc.org
215 N Dawson Street
Raleigh, NC 27603
Albert Coates Local Government Center
919-715-2893
Web Site: http://www.ncacc.org/
Email: ncacc@ncacc.org
Todd McGee, Communications Director
(919) 715-7336, or **todd.mcgee@ncacc.org**
Kevin.leonard@ncacc.org

NC League of Municipalities
Erin Wynia
ewynia@nclm.org
215 N Dawson Street
Raleigh, NC 27603
PO Box 3069 (27602-3069)
(919) 715-4000
Web Site: http://www.nclm.org/Pages/default.aspx

Professional Engineers of North Carolina
1015 Wade Ave, Suite A
Raleigh, NC 27605
(919) 834-1144 (phone)
E-Mail: exec@penc.org
Web Site: www.penc.org
Marc R. Worth, President
PSNC Energy
4077 Haywood Rd
Mills River, NC 28759
Phone: 828-890-7554
Email**:** mworth@scana.com
(in the future send directly to Betsy Bailey at bbailey@penc.org.)

National Federation of Independent Businesses – North Carolina
150 Fayetteville Street
Suite 1110
Raleigh, NC 27601
919-833-9480
Gregg Thompson, NFIB/North Carolina State Director
Gregg.Thompson@NFIB.org
Web Site: http://www.nfib.com/north-carolina

NC Council of Governments (NCCOGS):
Southwestern Commission, Land-of-Sky Regional Council, Isothermal Planning and Development Commission, High Country COG, Western Piedmont COG, Centralina COG, Piedmont Triad COG, Northwest Piedmont COG, Triangle J COG, Kerr-Tar Regional COG, Upper Coastal Plain COG, Mid-Carolina COG, Lumber River COG, Cape Fear COG, Eastern Carolina COG, Mid-East Commission, Albemarle Commission, Regional Associate.

NCCOGS Contact Information:

Southwestern Commission

(Region A)
Bill Gibson, Executive Director
Main Street Federal Building, Room 202
P.O. Drawer 850
Bryson City, NC 28713
Tel: (828) 488-9211 or Fax: (828) 488-3950
Email: bill@regiona.org
Website: www.regiona.org

Members: Cherokee, Clay, Graham, Haywood, Jackson, Macon and Swain Counties

Land-of-Sky Regional Council

(Region B)
Joe McKinney, Executive Director
339 New Leicester Hwy Asheville, NC 28806
Tel: (828) 251-6622 or
Fax: (828) 251-6353
jmckinney@landofsky.org
Email: info@landofsky.org
Website: www.landofsky.org

Members: Buncombe, Madison, Henderson, and Transylvania Counties

Isothermal Planning and Dev. Commission

(Region C)
Jim Edwards, Executive Director
jedwards@regionc.org
111 West Court Street
P.O. Box 841
Rutherfordton, NC 28139
Tel: (828) 287-2281 or Fax: (828) 287-2735
Website: www.regionc.org

Members: Cleveland, McDowell, Polk, and Rutherford Counties

High Country Council of Governments

(Region D)
Rick Herndon, Executive Director
Executive Arts Building, 155 Furman Road
P.O. Box 1820
Boone, NC 28607
Tel: (828) 265-5434 or Fax: (828) 265-5439
Email: rherndon@regiond.org
Website: www.regiond.org

Members: Alleghany, Ashe, Avery, Mitchell, Watauga, Wilkes, and Yancey Counties

Western Piedmont Council of Govt's

(Region E)
H. DeWitt Blackwell, Jr. AICP
Executive Director
Western Piedmont Council of Governments
P. O. Box 9026
Hickory, NC 28603 or
736 Fourth Street SW
Hickory, NC 28602
dee.blackwell@wpcog.org
828 485-4230 voicemail
828 455-3477 cell
828 322-5991 Fax
http://www.wpcog.org/

Members: Alexander, Burke, Caldwell, and Catawba Counties

Centralina Council of Governments

(Region F), Executive Director
Jim Prosser
Executive Director
525 North Tryon Street
12th Floor
Charlotte, NC 28202
jprosser@centralina.org
Tel: (704) 372-2416 or Fax: (704) 347-4710
Website: www.centralina.org

Member: Anson, Cabarrus, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, & Stanly Counties

Piedmont Triad Council of Governments
(Region G)
Ginger Booker, ***Interim*** Executive Director
2216 W. Meadowview Road, Suite 201
Wilmington Building
Greensboro, NC 27407-3408
Tel: (336) 294-4950 or Fax: (336) 632-0457
(Cy Stober, Water Resources Manager
cstober@ptcog.org

Website: www.ptcog.org

Members: Alamance, Caswell, Davidson, Guilford, Montgomery, Randolph, & Rockingham Counties

Northwest Piedmont Council of Govt's

(Region I)
Matthew L. Dolge, Executive Director
400 West Fourth Street, Suite 400
Winston-Salem, NC 27101
Tel: (336) 761-2111 or Fax: (336) 761-2112
TDD: (336) 761-2110
Email: regioni@nwpcog.org
Website: www.nwpcog.org

Members: Davie, Forsyth, Stokes, Surry, and Yadkin Counties

Triangle J Council of Governments

(Region J)
Kirby Bowers, Executive Director
kbowers@tjcog.org
4307 Emperor Blvd., Suite 110, Durham, 27703
Mailing address: P.O. Box 12276
Research Triangle Park, NC 27709
Tel: (919) 549-0551 or Fax: (919) 558-9393
Email: tjcog@tjcog.org
Website: www.tjcog.org

Members: Chatham, Durham, Johnston, Lee, Moore, Orange, and Wake Counties

Kerr-Tar Regional Council of Governments
(Region K)
Timothy Baynes
tbaynes@kerrtarcog.org , Executive Director
(timmy@kerrtarcog.org)
510 Dabney Drive
P.O. Box 709
Henderson, NC 27536
Tel: (252) 436-2040 or Fax: (252) 436-2055
Email:
Website: www.kerrtarcog.org

Members: Franklin, Granville, Person, Vance, and Warren Counties

Upper Coastal Plain Council of Govt's
(Region L)
Greg T. Godard, Executive Director
1309 S. Wesleyan Blvd. (37803)
P.O. Box 9
Wilson, NC 27894
Tel: (252) 234-5952
Email: ggodard@ucpcog.org
Website: www.ucpcog.org

Members: Edgecombe, Halifax, Northampton, Nash, and Wilson Counties

Mid-Carolina Council of Governments
(Region M)
James Caldwell, Executive Director
130 Gillespie Street
P.O. Drawer 1510
Fayetteville, NC 28302
Tel: (910) 323-4191 or Fax: (910) 323-9330
Email: jcaldwell@mccog.org
Website: www.mccog.org

Members: Cumberland, Harnett, and Sampson Counties

Lumber River Council of Govt's
(Region N)
James Perry, Executive Director
james.perry@lumberrivercog.org
Lumber River Council of Governments
30 CJ Walker Road
COMtech Park
Pembroke, NC 28372
Tel: (910) 618-5533 or
Website: http://www.lumberrivercog.org/
Email: lrcog@lrcog.org

Members: Bladen, Hoke, Richmond, Robeson, and Scotland Counties

Cape Fear Council of Govt's
(Region O)
Christopher D. May, Executive Director
1480 Harbour Drive
Wilmington, NC 28401
Tel: (910) 395-4553 or
Fax: (910) 395-2684
Email: cmay@capefearcog.org
Website: www.capefearcog.org
Contact: Don Eggert, Local Gov't Services Director
deggert@capefearcog.org

Members: Brunswick, Columbus, New Hanover, and Pender Counties

Eastern Carolina Council of Govt's

(Region P)
Larry Moolenaar, Executive Director
lmoolenaar@eccog.org
233 Middle Street, 3rd floor, O'Marks Bldg.
P.O. Box 1717
New Bern, NC 28563-1717
Tel: (252) 638-3185 or Fax: (252) 638-3187
Email: eccog@eccog.org
Website: www.eccog.org

Members: Carteret, Craven, Duplin, Greene, Jones, Lenoir, Onslow, Pamlico, Wayne Counties

Mid-East Commission
(Region Q)
Tim Ware, Executive Director
1385 John Small Avenue
P.O. Box 1787
Washington, NC 27889
Tel: (252) 974-1825
Email: tware@mideastcom.org
Website: http://www.mideastcom.org/
Phone: 252.946.8043
Toll Free: 1.800.799.9194

Members: Beaufort, Bertie, Hertford, Martin, and Pitt Counties

Albemarle Commission
(Region R)
Mr. Lambert, Executive Director
512 S. Church Street
P.O. Box 646
Hertford, NC 27944
Tel: (252) 426-5753 or
Fax: (252) 426-8482
slambert@albemarlecommission.org
Email: bkr27944@yahoo.com (? Did not send email)
http://www.albemarlecommission.org/

Members: Camden, Chowan, Currituck, Dare, Gates, Hyde, Pasquotank, Perquimans, Tyrrell, and Washington Counties

Regional Associate
William A. McNeil, AICP
Cell: (919) 622-3303
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Email: ncregions@mindspring.com

NC Association of Launderers & Cleaners
Sto Fox, Executive Director
stofox@ncalc.org
336-549-5486
1403-A Sunset Drive
Greensboro, NC 27408
336-389-9011
Web Site: http://www.ncalc.org/
Email: ncalc@ncalc.org
Charlie Smith, District 2 Director
charlie@crsassociates.org

North Carolina Farm Bureau
Mailing Address:
PO Box 27766
Raleigh, NC 27611
Physical Address:
5301 Glenwood Ave.
Raleigh, NC 27612
919 782-1705
http://www.ncfb.org/
Contact: Anne Coan
Anne.coan@ncfb.org
919-788-1005

Ncwaterworks operators association
http://wwww.ncwoa.com/
Leslie Carreiro, President
City of Asheville – North Fork WTP
3374 North Fork-Left Fork Rd, Black Mountain, NC 28711
Phone: 828-271-6105 Fax: 828-271-6102
lcarreiro@ashevillenc.gov
Cindy Gall, Administrator NCWOA
PO Box 4519
Emerald Isle, NC 28594
Phone: (252) 764-2094
Fax: (252) 764-2095
Email: ncwoa@intrex.net

North Carolina Poultry Federation
Kendall Casey, President
4020 Barrett Drive
Suite 102
Raleigh, NC 27609
Phone: (919) 783-8218
http://www.ncpoultry.org/
rlford@ncpoultry.org

Email Outreach to State Departments and Programs

North Carolina Department of Agriculture and Consumer Services (NCDACS)
Mr. Dewitt Hardee
Environmental Programs Manager
1001 Mail Service Center
Raleigh, NC 27699-1001
Dewitt.hardee@ncagr.gov
http://www.ncagr.gov/environmentalprograms/staff.htm

NC Department of Transportation
Ken D. Pace, State Environmental Operations Engineer
Roadside Environmental Unit
Environmental Operations & Rest Area
1557 Mail Service Center, Raleigh, NC 27699 (Mail)
1 South Wilmington Street, Raleigh, NC (Delivery)
Transportation Building - 5th Floor Annex
kpace@ncdot.gov
919 733-2920 x70

T. C. Niver, PG, CHMM - 1-888-457-0512
tniver@dot.state.nc.us
Roadside Environmental Unit
Environmental Operations Section
Environmental Operations Engineer III
1566 Mail Service Center (Mail)
Raleigh, NC 27699
4809 Beryl Road (office trailer)- Delivery
Raleigh, NC 27606

Robin Maycock
Environmental Operations Engineer II
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1425 Rock Quarry Road, Suite 106 (Delivery)
Raleigh, NC 27610
rmaycock@ncdot.gov
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John Kirby
jkirby@ncdot.gov
508-1816

NCDENR Division of Environmental Health
Terry Pierce, Director
2728 Capital Blvd.
1630 MSC
Raleigh NC 27699-1630
Phone: (919) 733-2870
Fax: (919) 715-3242
Terry.pierce@ncdenr.gov

NC Division of Water Resources, Tom Reeder, Director
Tom.reeder@ncdenr.gov
919-715-3045
Public Water Supply Section (now under DWR)
Jessica Godreau, P.E., CPM, Section Chief
(919) 715-3232
Jessica.godreau@ncdenr.gov
PWSS Web site: http://www.ncwater.org/pws/

North Carolina Division of Air Quality
Sheila Holman, Director
Sheila.holman@ncdenr.gov
1641 Mail Service Center
Raleigh, NC 27699-1641
(919) 715-0971

North Carolina Division of Waste Management
Dexter Matthews, Director
Linda Culpepper, Deputy Director
1646 Mail Service Center,
Raleigh, NC 27699-1646
(919)508-8400

NC DWQ Aquifer Protection Section
Ted Bush, Chief
919-715-6172
Betty Wilcox
715-6169

NC DHHS Division of Public Health
Mina W. Shehee, Ph.D.
Medical Evaluation & Risk Assessment Unit
Occupational & Environmental Epidemiology Branch
Division of Public Health
North Carolina Department of Health & Human Services
1912 Mail Service Center
Raleigh NC 27699-1912
(919) 707-5920
mina.shehee@dhhs.nc.gov
ken.rudo@dhhs.nc.gov

Email Outreach to Environmental Groups:

Clean Water for North Carolina
Hope Taylor-Guevara, Executive Director
Durham Office
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hope@cwfnc.org
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NC Conservation Network
Grady McCallie, Policy Director
19 E. Martin St., Suite 300
Raleigh, NC 27601
919.857.4699
grady@ncconservationnetwork.org
Dan Conrad
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Environmental Defense Fund
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Maggie Clary
mclary@edf.org

Southern Environmental Law
Mary Maclean Asbill
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Julie Youngman
jyoungman@selcnc.org
Geoff Gisler
ggisler@selcnc.org
NC/SC Office
200 West Franklin St., Suite 330
Chapel Hill, NC 27516-2559
(919) 967-1450
Fax (919) 929-9421
Note: sent information in an email through their web site "send us an email" link. Could not find an email address for any staff online.

American Rivers
Peter Raabe
praabe@americanrivers.org
331 West Main Street
Suite 504
Durham NC 27701
919-682-3500

AWWA (NC American Waterworks Association)
Nbanks@ncsafewater.org
Lindsay Roberts, Executive Director
lrobertrs@ncsafewater.org

NC League of Conservation Voters (formerly Conservation Council of North Carolina)
Dan Crawford
dan@nclcv.org
http://www.nclcv.org/

NC Sierra Club
http://nc.sierraclub.org/about/contact.html
info@sierraclub-nc.org

Molly Diggins, State Director

Western NC Alliance (WNCA)
Julie Mayfield, Executive Director
www.wnca.org
julie@wnca.org

Waterkeepers
Hannah Connor
hconnor@waterkeeper.org

Others contacted as a result of outreach:

Drycleaning and Laundry Institute
Mary Scalco
mscalco@ifi.org
1-800-638-2627
704-216-8593

S&ME, Inc.
Connel Ware
Senior Project Manager
3718 Old Battleground Road
Greensboro, NC 27410
336-288-8980
cware@smeinc.com

ARCADIS U.S., Inc.
801 Corporate Center Drive, Suite 300
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919-854-1282
Shawn Sager, Ph.D. Principal Scientist
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Rhodia, Inc.
207 Telegraph Drive
Gastonia, NC
Benne Hutson
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Utilities Inc. (aka Carolina Water)
Mary Rollins
704-319-0519
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American Truetzschler
John Guglielmetti
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Excel Civil & Environmental Associates, PLLC
Mike Stanforth
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Middlesex Public Water Supply
Tony Arnold, Director of Client Services
Envirolink, Inc.
Phone: 252-235-4900
Cell: 252-236-8168
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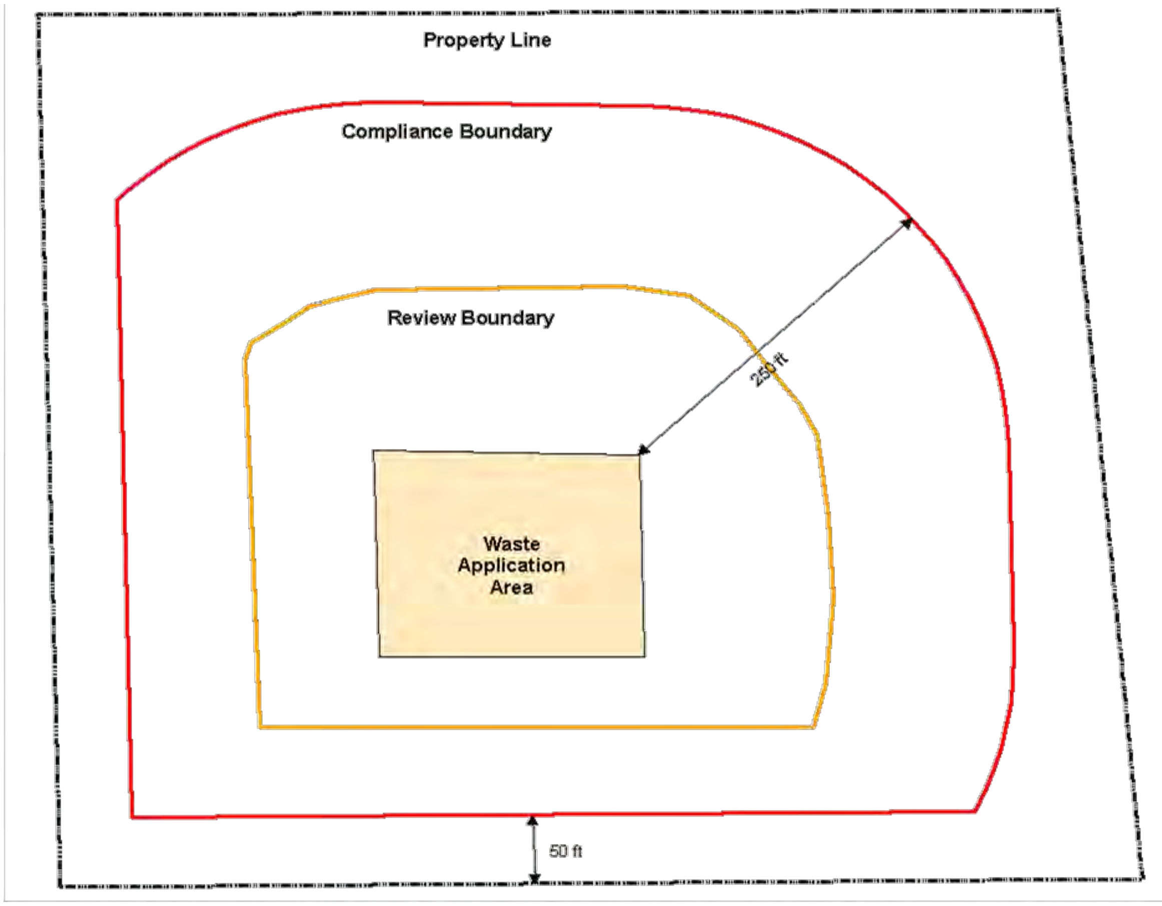
APPENDIX J: Boundaries at a Typical DWQ Permitted Waste Site



- A Compliance Boundary (CB) is determined at a specific distance from the Waste Boundary
- The Review Boundary (RB) is midway between the CB and the RB
- Exceedances of the groundwater quality standard at the Review Boundary (RB) require preventive action/ modeling; exceedances at the Compliance Boundary (CB) require corrective action.

As shown: “For disposal systems individually permitted on or after December 30, 1983, a compliance boundary shall be established 250 feet from the waste boundary, or 50 feet within the property boundary, whichever point is closer to the source.” 15A NCAC 02L.0107(b)

“For disposal systems individually permitted prior to December 30, 1983, the compliance boundary is established at a horizontal distance of 500 feet from the waste boundary or at the property boundary, whichever is closer to the source.” 15A NCAC 02L.0107(a)

“A review boundary is established around any disposal system midway between the compliance boundary and the waste boundary.” 15A NCAC 02L.0108

Appendix K
0-10 Years
Costs and Benefits Associated with Proposed Rule Changes to 15A NCAC 02L .0202 Groundwater Quality Standards with Two Percent Inflation and Seven Percent Discount Rate

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**2017-18**	**2018-19**	**2019-20**	**2020-21**	**2021-22**
Year Number	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Costs											
Private Company Well Closure Costs	$0	$5,304	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	***$0***	***$5,304***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***
Benefits											
State Benefits											
DOT Reduced Monitoring	$0	$3,672	$3,537	$3,396	$3,247	$3,091	$2,928	$2,757	$2,578	$2,390	$2,194
DWM Opportunity Cost Savings											
Private Company Benefits											
Monitoring Cost Savings to Private Companies	$0	$5,426	$5,535	$5,646	$5,759	$5,874	$5,991	$6,111	$6,233	$6,358	$6,485
Operations and Maintenance Cost Savings		$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Benefits	***$0***	***$9,098***	***$9,072***	***$9,041***	***$9,006***	***$8,965***	***$8,919***	***$8,868***	***$8,811***	***$8,748***	***$8,679***
Net Impact (benefits-costs)	**$0**	**$3,794**	**$9,072**	**$9,041**	**$9,006**	**$8,965**	**$8,919**	**$8,868**	**$8,811**	**$8,748**	**$8,679**
Total Impact (benefits+costs)	***$0***	***$14,402***	***$9,072***	***$9,041***	***$9,006***	***$8,965***	***$8,919***	***$8,868***	***$8,811***	***$8,748***	***$8,679***
Net Present Value	**$895,775**										

Appendix K

11-20 Years

Costs and Benefits Associated with Proposed Rule Changes to 15A NCAC 02L .0202 Groundwater Quality Standards with Two Percent Inflation and Seven Percent Discount Rate

Fiscal Year	**2022-23**	**2023-24**	**2024-25**	**2025-26**	**2026-27**	**2027-28**	**2028-29**	**2029-30**	**2030-31**	**2031-32**
Year Number	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Costs										
Private Company Well Closure Costs	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***
Benefits										
State Benefits										
DOT Reduced Monitoring	$1,989	$1,776	$1,552	$1,319	$1,077	$824	$560	$286	$0	$0
DWM Opportunity Cost Savings						$1,145	$1,168	$1,191	$1,215	$1,239
Private Company Benefits										
Monitoring Cost Savings to Private Companies	$6,615	$6,747	$6,882	$7,020	$7,160	$0	$0	$0	$0	$0
Operations and Maintenance Cost Savings	$0	$0	$0	$0	$0	$219,646	$224,039	$228,519	$233,090	$237,752
Total Benefits	***$8,604***	***$8,523***	***$8,434***	***$8,339***	***$8,237***	***$221,614***	***$225,767***	***$229,996***	***$234,305***	***$238,991***
Net Impact (benefits-costs)	**$8,604**	**$8,523**	**$8,434**	**$8,339**	**$8,237**	**$221,614**	**$225,767**	**$229,996**	**$234,305**	**$238,991**
Total Impact (benefits+costs)	***$8,604***	***$8,523***	***$8,434***	***$8,339***	***$8,237***	***$221,614***	***$225,767***	***$229,996***	***$234,305***	***$238,991***
Net Present Value	**$895,775**									

Appendix K

21-30 Years

Costs and Benefits Associated with Proposed Rule Changes to 15A NCAC 02L .0202 Groundwater Quality Standards with Two Percent Inflation and Seven Percent Discount Rate

Fiscal Year	**2032-33**	**2033-34**	**2034-35**	**2035-36**	**2036-37**	**2037-38**	**2038-39**	**2039-40**	**2040-41**	**2041-42**
Year Number	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
Costs										
Private Company Well Closure Costs	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***
Benefits										
State Benefits										
DOT Reduced Monitoring	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
DWM Opportunity Cost Savings	$1,264	$1,289	$1,315	$1,341	$1,368	$1,396	$1,424	$1,452	$1,481	$1,511
Private Company Benefits										
Monitoring Cost Savings to Private Companies	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Operations and Maintenance Cost Savings	$242,507	$247,357	$252,304	$257,350	$262,497	$267,747	$273,102	$278,564	$284,135	$289,818
Total Benefits	***$243,771***	***$248,646***	***$253,619***	***$258,691***	***$263,865***	***$269,143***	***$274,525***	***$280,016***	***$285,616***	***$291,329***
Net Impact (benefits-costs)	**$243,771**	**$248,646**	**$253,619**	**$258,691**	**$263,865**	**$269,143**	**$274,525**	**$280,016**	**$285,616**	**$291,329**
Total Impact (benefits+costs)	***$243,771***	***$248,646***	***$253,619***	***$258,691***	***$263,865***	***$269,143***	***$274,525***	***$280,016***	***$285,616***	***$291,329***
Net Present Value	**$895,775**									

Appendix L

0 – 10 years

Private Industry Costs and Benefits with the Proposed Rule Change

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**2017-18**	**2018-19**	**2019-20**	**2020-21**	**2021-22**
Year Number	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Costs											
Well Closure Costs	$0	$5,304	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	***$0***	***$5,304***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***
Benefits											
Monitoring Cost Savings	$0	$5,426	$5,535	$5,646	$5,759	$5,874	$5,991	$6,111	$6,233	$6,358	$6,485
Operations and Maintenance Cost Savings	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Benefits	***$0***	***$5,426***	***$5,535***	***$5,646***	***$5,759***	***$5,874***	***$5,991***	***$6,111***	***$6,233***	***$6,358***	***$6,485***
Net Impact (benefits-costs)	**$0**	**$122**	**$5,535**	**$5,646**	**$5,759**	**$5,874**	**$5,991**	**$6,111**	**$6,233**	**$6,358**	**$6,485**
Total Impact (benefits+costs)	***$0***	***$10,730***	***$5,535***	***$5,646***	***$5,759***	***$5,874***	***$5,991***	***$6,111***	***$6,233***	***$6,358***	***$6,485***
30-year Net Present Value	**$866,145**										

Appendix L

11 – 20 years

Private Industry Costs and Benefits with the Proposed Rule Change

Fiscal Year	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29	2029-30	2030-31	2031-32
Year Number	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Costs										
Well Closure Costs	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***
Benefits										
Monitoring Cost Savings	$6,615	$6,747	$6,882	$7,020	$7,160	$0	$0	$0	$0	$0
Operations and Maintenance Cost Savings	$0	$0	$0	$0	$0	$219,646	$224,039	$228,519	$233,090	$237,752
Total Benefits	***$6,615***	***$6,747***	***$6,882***	***$7,020***	***$7,160***	***$219,646***	***$224,039***	***$228,519***	***$233,090***	***$237,752***
Net Impact (benefits-costs)	**$6,615**	**$6,747**	**$6,882**	**$7,020**	**$7,160**	**$219,646**	**$224,039**	**$228,519**	**$233,090**	**$237,752**
Total Impact (benefits+costs)	***$6,615***	***$6,747***	***$6,882***	***$7,020***	***$7,160***	***$219,646***	***$224,039***	***$228,519***	***$233,090***	***$237,752***
30-year Net Present Value	**$866,145**									

Appendix L

21 – 30 years

Private Industry Costs and Benefits with the Proposed Rule Change

Fiscal Year	**2032-33**	**2033-34**	**2034-35**	**2035-36**	**2036-37**	**2037-38**	**2038-39**	**2039-40**	**2040-41**	**2041-42**
Year Number	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
Costs										
Well Closure Costs	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Total Costs	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***
Benefits										
Monitoring Cost Savings										
Operations and Maintenance Cost Savings	$242,507	$247,357	$252,304	$257,350	$262,497	$267,747	$273,102	$278,564	$284,135	$289,818
Total Benefits	***$242,507***	***$247,357***	***$252,304***	***$257,350***	***$262,497***	***$267,747***	***$273,102***	***$278,564***	***$284,135***	***$289,818***
Net Impact (benefits-costs)	**$242,507**	**$247,357**	**$252,304**	**$257,350**	**$262,497**	**$267,747**	**$273,102**	**$278,564**	**$284,135**	**$289,818**
Total Impact (benefits+costs)	***$242,507***	***$247,357***	***$252,304***	***$257,350***	***$262,497***	***$267,747***	***$273,102***	***$278,564***	***$284,135***	***$289,818***
30-year Net Present Value	**$866,145**									

Appendix M

0-20 Years

Public Water Supply Systems Costs with the Proposed Change

Unadjusted For Future Inflation

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**2017-18**	**2018-19**	**2019-20**	**2020-21**	**2021-22**
Year Number	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Costs											
Estimated Capitol Expenditure											$226,800
Annual Operation & Maintenance											*$76,700*
Annual Monitoring											$600
Total Costs	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$304,100***
20 Year Net Present Value	**($509,168.69)**										

Fiscal Year	**2022-23**	**2023-24**	**2024-25**	**2025-26**	**2026-27**	**2027-28**	**2028-29**	**2029-30**	**2030-31**	**2031-32**
Year Number	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Costs										
Estimated Capitol Expenditure										$226,800
Annual Operation & Maintenance	*$76,700*	*$76,700*	*$76,700*	*$76,700*	*$76,700*	*$76,700*	*$76,700*	*$76,700*	*$76,700*	*$153,400*
Annual Monitoring	$600	$600	$600	$600	$600	$600	$600	$600	$600	$1,200
Total Costs	***$77,300***	***$77,300***	***$77,300***	***$77,300***	***$77,300***	***$77,300***	***$77,300***	***$77,300***	***$77,300***	***$381,400***
20 Year Net Present Value	**($509,168.69)**									

Appendix M

0-20 Years

Public Water Supply Systems Costs with the Proposed Change

Adjusted For Future Two Percent Inflation

Fiscal Year	**2011-12**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**2017-18**	**2018-19**	**2019-20**	**2020-21**	**2021-22**
Year Number	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Costs											
Estimated Capitol Expenditure		$0	$0	$0	$0		$0	$0	$0	$0	$276,468
Annual Operation & Maintenance		$0	$0	$0	$0	$0	$0	$0	$0	$0	$93,497
Annual Monitoring		$0	$0	$0	$0	$0	$0	$0	$0	$0	$731
Total Costs	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$0***	***$370,696***
20 Year Net Present Value	**($676,861.86)**										

Fiscal Year	**2011-12**	**2022-23**	**2023-24**	**2024-25**	**2025-26**	**2026-27**	**2027-28**	**2028-29**	**2029-30**	**2030-31**	**2031-32**
Year Number	**0**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Costs											
Estimated Capitol Expenditure		$0	$0	$0	$0	$0	$0	$0	$0	$0	$337,013
Annual Operation & Maintenance		$95,367	$97,274	$99,220	$101,204	$103,228	$105,293	$107,399	$109,546	$111,737	$227,944
Annual Monitoring		$746	$761	$776	$792	$808	$824	$840	$857	$874	$1,783
Total Costs	***$0***	***$96,113***	***$98,035***	***$99,996***	***$101,996***	***$104,036***	***$106,116***	***$108,239***	***$110,403***	***$112,612***	***$566,740***
20 Year Net Present Value	**($676,861.86)**										

Appendix N: Summary of Division of Waste Management Site Information

Name & Address	***DWM Program with Oversight ****	***Is 1,1-dichloroethylene (1,1-DCE) present in groundwater above 7 ug/L?***	***Is 1,1-dichloroethylene (1,1-DCE) present in groundwater above 350 u/L?***	**What constituent(s) are driving site assessment, remediation, and other action?**
Rhodia Inc. 207 Telegraph Drive Gastonia, NC	IHSB	Yes	Yes	1,1-DCE
Radiator Specialty 100 Radiator Road Indian Trail, NC	HWS	Yes	Yes	1,4-dioxane, PCE, TCE, 1,1-DCA, 1,2-DCA
Suttle Avenue, LLC Formerly Radiator Specialty Intersection of Wilkinson Blvd and Suttle Ave. Charlotte, NC	BFs 06016-02-60 HWS NCD003149663 Also in IHSB Inventory (1900 Wilkinson Ave)	No Maximum on site was 8.1 ug/L and it is now below 7 ug/L	No	PCBs and chlorinated solvents (PCE, TCE, vinyl chloride)
Intersection of Pearson's Turnpike and Chicksaw Road Gastonia Township, NC	BFs "MTE Hydraulics"	No	No	Known petroleum & chlorinated Solvent groundwater Contamination has been remediation to standard
The Park Ministries, Inc. 2500 Independence Blvd Charlotte, NC	BFs 10038-06-60 Know as "Merchandise Mart"	Yes 230 ug/L sampled on 02/02/06	No	No active remediation, only Land Use Restrictions. Risk drivers are chlorinated solvents 1,1-DCE, PCE & TCE. All above 2L standard
Camden Square: Design Center Carolinas, LLC 118-120 West Worthington Ave. Charlotte, NC	BFs	Yes 480 µg/L in MW-1 1,200 µg/L in MW-3	?	Chlorinated solvents
Intersection of Highway 321 and Rankin Lake Road Gastonia, NC	BFs 10063-06-36 Know as "Former ATS Manufacturing"	No Detected in three wells at 52 ppb, 49 ppb & 20 ppb but now below 7 ug/L	No	No active remediation, only Land Use Restrictions. Chlorinated solvents (1,1-DCE, PCE, 1,1,1-TCA) above 2L required a BFA.
Former Ashland, Inc. 1415 South Bloodworth St Raleigh, NC	HWS	Yes	No	PCE & degradation products (TCE, cis-1,2-DCE, vinyl chloride). Also present in significantly lower levels: 1,1-DCE,carbon tetrachloride, chloroform, 1,1-DCA, 1,1,1-TCA and methylene chloride
Former Ashland, Inc. 2802 Patterson Street Greensboro, NC	HWS	Yes	Yes	PCE, TCE and numerous other VOCs and SVOCs present above 2L.

(Inactive Hazardous Sites Branch (IHSB), Hazardous Waste Section (HWS), Brownfields Program(BFs)